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# HEALTH CARE REFORM (Part 9)

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Health Care Reform, (Part 9), Serial...

## HEARINGS BEFORE THE SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED THIRD CONGRESS SECOND SESSION

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FEBRUARY 2, 1994—ALTERNATIVE LEGISLATIVE APPROACHES  
FEBRUARY 3, 1994—LONG-TERM CARE AND QUALITY ASSURANCE  
FEBRUARY 8, 1994—PRESCRIPTION DRUG BENEFIT  
FEBRUARY 10, 1994—HEALTH EQUITY AND ACCESS REFORM

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**Serial No. 103-110**

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## HEALTH CARE REFORM

### Alternative Legislative Approaches

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WEDNESDAY, FEBRUARY 2, 1994

HOUSE OF REPRESENTATIVES,  
COMMITTEE ON ENERGY AND COMMERCE,  
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT,  
*Washington, DC.*

The subcommittee met, pursuant to notice, at 10:15 a.m., in room 2123, Rayburn House Office Building, Hon. Henry A. Waxman (chairman) presiding.

Mr. WAXMAN. The meeting of the subcommittee will come to order. Today's hearing continues our examination of alternative approaches to health reform.

Yesterday we heard testimony on the proposal offered by Mr. McDermott, H.R. 1200, that would achieve universal coverage through a single payer approach. We also received testimony on H.R. 3080, sponsored by Representative Michel, that would require all employers to offer but not contribute to health insurance to their workers and dependents.

This morning we are going to look at H.R. 3222, the Managed Competition Act of 1993, introduced by our colleague Mr. Cooper, and cosponsored by several other members of the committee. Unlike President Clinton's proposal and unlike Mr. McDermott's bill, H.R. 3222 would not guarantee health coverage to all Americans and would not establish limits on increases in health care costs.

This afternoon we will hear from members with other proposals relating to health care reform. Among the witnesses will be our colleagues, Mr. Rowland and Mr. Bilirakis, testifying in support of H.R. 3573, the Community Health Improvement Act of 1993. In addition, Mr. Stearns from the subcommittee on Commerce, Consumer Protection, and Competitiveness will testify on H.R. 3698, the Consumer Choice Health Security Act.

Before calling on our first witnesses, I would like to recognize the distinguished ranking member of the subcommittee, Mr. Bliley, for any opening statement he may have. Without objection, all members' opening statements will be inserted in the record at this point in full.

Mr. BLILEY. Thank you, Mr. Chairman.

It has been a little over a week since the State of the Union address in which the President showed us his "veto pen" and threatened to veto any bill which does not employ immediate universal coverage through a nationalized system. Rather than responsibly attempt to accomplish bipartisan reform which will fix the prob-

lems in the insurance marketplace that the President himself identified, such as preexisting conditions, continuity of coverage, guaranteed renewability and no medical underwriting, he would rather hold out for a nationalized, command and control, "one-size-fits-all" health care system which relies on rationing and limiting individual choice. The only two bills which meet these criteria are his Health Security Act and the McDermott Canadian single payer bill.

Both these bills lead to a national health care system with global budgets, price controls and new payroll and individual taxes. These bills terminate every American's current health insurance coverage and place everyone permanently in government-controlled entitlement programs run by Federal and State bureaucrats. Fourteen percent of our economy would be under the command and control of a National Health Board located in Washington, D.C., and now we can look to the experience of our Canadian neighbors, who had to shut down their hospitals for 3 weeks during Christmas because the government ran out of money.

When asked about this shutdown, the President of the largest hospital in Toronto stated, "This is not about health care; this is about the deficit."

One example of the treatments affected by the shutdown is described by one of Toronto's leading orthopedic surgeons, Dr. Robert Bell. He stated that three of his bone cancer patients had to be sent elsewhere for 2 weeks during the shutdown. He states that "The delay will not reduce the patient's life span, but it will extend the duration of their pain. Their discomfort level has been increased by weeks."

Dr. Bell, who practiced medicine for 2 years in Boston, further stated, "If you said to an American patient, 'We are going to delay your surgery for 2 weeks because costs are involved,' they would never accept it." Well, Dr. Bell, I hope you are right.

Yesterday, the distinguished Minority Leader, Bob Michel, testified with my colleagues, Congressmen Hastert and Thomas, on H.R. 3080, the Affordable Health Care Act of 1993. This bill has 138 cosponsors, more than any other health reform bill. It provides targeted fixes for specific problems in the health care marketplace. It is a bill which provides universal access for all Americans without rationing health care and taking away every American's private health insurance.

Today, our first three panels will discuss H.R. 3222, the Managed Competition Act of 1993, cosponsored by our distinguished colleague, Congressman Cooper. This bill is particularly interesting for several reasons. First, it is truly the only current bill which has some limited bipartisan support in both the House and Senate. And because this bill has some bipartisan support, the administration has sent out "its storm troopers" and public interest group "hacks" in a "search and destroy" mission to kill it. But so far the administration's efforts have more of the "look and feel" of the "old Keystone Kops."

In today's environment, it seems that it is a punishable offense to sponsor a health care reform bill that does not guarantee immediate universal coverage for everyone. Today, respected members from both parties are given failing marks if they refuse to embrace a universal entitlement program for health care, particularly one



built upon tollgates, CPI premium caps, national boards and giant health alliances which will provide health care for almost all Americans in large managed care entities. The failing grades should go to the Cabinet Secretaries, OMB officials and HHS bureaucrats who have paraded before this subcommittee for over 20 hearings and have not been able to explain the basic features of the administration's bill. In more than a few instances, they didn't even know what was in the bill.

Like many of us, my colleague from Tennessee is walking a fine line in attempting to build a delicate balance. Some days the press reports he is at the White House for discussions. Other days the administration identifies him as "Public Enemy Number One" in the health care debate.

We on this side of the aisle want to keep the lines of communication open. There is great interest in a Bipartisan approach, and I would like to remind my colleague from Tennessee that health care reform cannot be accomplished in a meaningful way without unified, mainstream Republican support.

The Managed Competition Act of 1993 is a complicated bill. But, like the Republican Health Task Force bill, it attempts to fix the problems in the health insurance marketplace that need to be corrected. Although at this point in the debate I cannot support a tax cap because it is a tax increase on working Americans, or State-controlled mandatory alliances, I want to congratulate our colleague, Congressman Cooper, for producing a bill which refuses to embrace global budgets, price controls or an employer mandate.

I am also happy to see that the bill's malpractice reform and administrative simplification sections are similar to the Republican Health Task Force bill. Yours is a bill that builds on the strengths of the current system, which is the finest health care system in the world. And it does this by refusing to ration health care, limit patient choice, create an employer mandate, and generally turn the American health care system into a second rate one.

I sincerely hope in the upcoming weeks, that members from both parties, who are interested in both reforming and preserving the world's finest health care system, can work together in the spirit of cooperation. "Veto Pens," "Name Calling," and "Mud Slinging" will never advance the debate on such a monumental issue.

Mr. WAXMAN. Mr. Wyden.

Mr. WYDEN. I think the gentleman from Virginia is absolutely right in saying how important it is to keep the lines of communication open. Having spent, I would say, hundreds of hours over the years talking with Congressman Cooper, I know he is committed to that and that his heart is in the right place.

Mr. Chairman, I really have three substantive concerns about the Cooper legislation. First is, if you want a significant role for the private sector in health care, you have to deal with the problem of cost-shifting.

We know that about two-thirds of the employers in this country cover their people for health care; about a third don't. We are, in effect, paying the hospital emergency room bills of those employers that don't cover their people by shifting those costs onto the employers that do.

It seems to me that the Cooper legislation, in effect, surrenders in the fight against cost-shifting. It simply walks away from that battle.

I know my friend feels that the way you deal with cost-shifting is by reforming Medicare. I would say to him, as we have said over a number of conversations, we have to have shared responsibility where the employer covers a portion, the employee covers a portion, rather than to surrender in the fight against cost-shifting, as I believe the Cooper legislation does.

My second point is that I think the Cooper legislation walks away from the rights of millions of women in our country. The fact is, women are guaranteed under the law the right of free choice, the right to choose with respect to abortion; millions of them have that right protected in their private health insurance policies. The Cooper legislation does not ensure that right of free choice, and I think that is unfortunate.

The third area I think the bill is deficient in deals with medical technology. I am surprised at the approach my friend takes on this because, in effect, he takes the piece that is driving up medical costs, medical technology, and just hands it over to a government agency. I and others would like to incentivize the private sector through a voluntary approach on technology where companies would be given a voluntary incentive to show where their technology is superior to others. I am hopeful that we can work with our colleague on that.

Mr. Chairman, let me again say I think Jim Cooper's heart is in the right place. We have a debate about how to get this job done, but this is a thoughtful member who means well, and I look forward to continuing to work with him; and I yield back.

Mr. WAXMAN. Thank you.

Mr. Greenwood.

Mr. Klug.

Mr. KLUG. Let me echo the comments of my colleague Mr. Wyden that Jim Cooper's and Fred Grandy's hearts are in the right place, and I suspect their heads are also in the right place; but I think what has happened with the Cooper-Grandy-Andrews bill, which I and a number of Republicans and Democrats are cosponsors on, is that it reflects best the traditional ideas of the Jackson Hole model where the private sector maintains a role in health care reform and where we understand the government has very limited ability to run the whole system.

The Cooper-Grandy bill, it seems to me, does the best job of intervening to correct the problems we all see right now in the health insurance area, but at the same time steps back and does not have the government too heavily involved in the system. It does not repeat the President's mistake of employer mandates.

I will be interested to hear Mr. Cooper's and Mr. Grandy's thoughts on Hawaii's experience, where we have had an employer mandate in place for some time that still does not achieve universal coverage. Perhaps importantly for my district, it still allows a great deal of flexibility in terms of self-insured programs. I have several major employers in my district who estimate their health insurance costs under the President's plan could rise \$2 million



next year and you don't need a doctorate in economics to understand that will mean layoffs and problems for the private sector.

Let me also express my thanks to my colleagues for avoiding the mistakes of price controls or global budgets. If we are going to try to hold down costs in the health care system, I think we should do it consciously rather than assume, if we set some artificial limits, that it will squeeze out inefficiencies. Instead, we may see what Mr. Bliley suggested in the case of Canada. You squeeze out coverage and care that is very necessary and obviously justifiable by any kind of medical experience.

I look forward to hearing my colleagues' thoughts, and congratulate Jim and Fred for putting together the best bipartisan bill which I think does the best job of reflecting the government's role in the health care crisis.

Mr. WAXMAN. Thank you, Mr. Klug.

Mr. Kreidler.

Mr. KREIDLER. I would like to add my support to the proposal that is before us from the standpoint of its thoughtfulness and comprehensiveness. However, I would have to say that I have some reservations about how well it will address the two overriding concerns of health care reform.

Number one is that it must achieve universal coverage, not only because it is the right and the fair thing to do, but also because you have to end this interminable cost-shifting between individuals who don't pay and individuals who pay more than their fair share, and employers who play the same role. I am afraid this legislation would come up short on that scale.

If it could achieve that goal, I think we would feel much more comfortable about it because it is one of the driving economic issues that is involved.

The second is, I am concerned that it does not set in place the kinds of cost controls that are going to be so critical to slow down spending on health care in this country, not spend less, just so we hold it down, so we are only spending at the inflation rate, as opposed to two and three times the inflation rate.

But I commend the sponsors, Messrs. Cooper and Grandy, for proposing this legislation. It is indeed well thought out, comprehensive; it is the kind of legislation we should have in front of us as a part of this debate. It is unfortunate that more members have not embraced this kind of comprehensive approach, who still look and say, "What happens to Americans who go bankrupt because of health care needs, what happens when government goes bankrupt is not our concern, we can turn our back on these issues and say that doesn't matter to us, all we have to do is preserve the status quo."

We know what the status quo is doing to us. In the words of Senator Dole when he cosponsored President Nixon's health care reform back in the early 1970's, we had a crisis 20 years ago, indeed we have a crisis today.

That legislation called for an employer mandate. I think an employer mandate is probably the most effective tool, something not included in this legislation, something that I feel would help to perfect it to the point where we are able to accomplish the goals of

universal coverage and cost control in our health care system. But I commend the gentlemen for their proposal.

Thank you, Mr. Chairman.

Mr. WAXMAN. Mr. McMillan.

Mr. McMILLAN. Thank you, Mr. Chairman.

As a cosponsor of the Cooper-Grandy bill, I want to welcome you. I don't agree with 100 percent of it, but I also don't agree with 100 percent of the Republican alternative, which I helped shape.

Everyone should be aware that there are close to 140 cosponsors on the Republican bill. There are over 60 cosponsors on the Cooper-Grandy bill, half of whom are Republicans, half of whom are Democrats. There are 101 cosponsors of the President's bill, half of whom are also single-payer advocates, so in effect the President has attracted only 50 cosponsors to his bill.

I remind the gentleman from Washington that if you are going to get anything through the Congress, you will have to get people like Senator Dole to support it. We have to come together on things that we agree are important and not fall apart on those things that we disagree on. It is in that spirit that I think that what the two gentlemen have proposed is extraordinarily constructive and gets at a lot of the major problems.

It is rank hypocrisy to talk about this bill as not addressing cost-shifting, because it does effectively address cost-shifting in the private sector; to the extent that that has been imposed by private insurers, it gets at that in a competitive fashion. The President's plan would address cost-shifting only through price-fixing and not through competition, which in the end it would tend to diminish. It is rank hypocrisy because the President's plan and all plans fail to get at the major cause of cost-shifting, and that is Medicare.

Medicare is not included in any of the plans. It is one of the problems I have with all the plans, and it is really tough but there are ways to do that.

If we don't take advantage of the opportunity to incorporate Medicare into health care reform at this juncture, we are going to be faced with the kind of decisions that we will be faced with under the President's plan, in which he is going to ask us to adopt major new entitlement programs covering the senior population, costing \$131 billion; and then he is going to come back and say he is going to pay for it with money he expects us to save by cutting Medicare \$124 billion, which history has shown he won't do.

So I think it is hypocritical to deal with Medicare in the fashion that the President has proposed.

My time has expired, and maybe we can get to some of these points in the questioning. I want to thank the gentlemen for the constructive efforts that they are making. Any constructive effort that this Congress is going to succeed in achieving in this session has got to be based on bipartisan support, and I dare say that it is probably going to have to be about 50/50 in order to pass anything. So I look forward to our questioning and yield back the balance of my time.

Mr. WAXMAN. Thank you.

Mr. Brown.

Mr. BROWN. No opening statement, Mr. Chairman.

Mr. WAXMAN. Mr. Paxon.



Mr. PAXON. No opening statement, Mr. Chairman.

Mr. WAXMAN. Our first panel this morning includes two of our colleagues, sponsors of H.R. 3222, the Managed Competition Act of 1993—our subcommittee colleague, the Honorable Jim Cooper of Tennessee and the Honorable Fred Grandy of Iowa, a member of the Committee on Ways and Means.

Thank you for being here. Your prepared statements, without objection, will be made part of the record in their entirety. We would like to ask you to proceed with your testimony, and we would appreciate if you would limit it to 5 minutes.

Mr. Cooper, let's start with you.

**STATEMENT OF HON. JIM COOPER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE**

Mr. COOPER. Thank you, Mr. Chairman. I would like to ask unanimous consent to submit two documents for the record.

Mr. WAXMAN. Without objection.

Mr. COOPER. I would also like to thank you for holding this hearing. No other Member of Congress combines your skill as a legislator with your knowledge of health care. It is an honor to be a member of your subcommittee and to appear before you and my colleagues as a witness. I wish that you were a supporter of our bill, but I am confident that we can work together to make sure that the dream of national health reform is achieved this year.

I am particularly grateful to my colleague, Scott Klug, perhaps my earliest cosponsor, who has been a great help in formulating this legislation throughout the process, including in the last Congress. It was vitally important. I appreciate the cosponsorship of my colleague, Alex McMillan, and also the cosponsorship of Mike Synar and now Bill Richardson on our bill. Some others of you haven't cosponsored it yet, but we have learned from your expertise. My colleagues Ron Wyden, Mike Kreidler and Tom Bliley have been very helpful in helping us put together some of these ideas.

Mr. Chairman, in our committee's long and distinguished history, this subcommittee may never have faced a more daunting task. We have been given 1 month to decide how to fix the cost and access problems in today's health care system. Not since the Great Society, and perhaps not since the New Deal, have changes of this magnitude been contemplated with such a tight deadline.

As my colleagues decide which reform strategy to pursue, I would urge everyone to be genuinely bipartisan. I know this sounds simple, and it is certainly a goal to which everyone at least pays lip service. But it is the only way to pass a bill through the Senate. It is the only way to get a bill through the House of Representatives with the large majority that the historic bills of this century have had.

Far more important than passing Congress, bipartisanship is vital to making sure that health care reform really works back home in every town and city in America, because we need to pass a plan that makes all of our patients feel comfortable whether they are Democrats, Republicans, Independents or don't care a thing about politics.

The President and the First Lady deserve tremendous credit for their leadership in health reform. As the former Surgeon General,

Dr. C. Everett Koop, said, the Clintons have already accomplished more in health care reform than all their living predecessors put together. We think the President and First Lady have a historic opportunity to lead an overwhelming majority of us toward a bipartisan solution to health reform this year.

We are closer to that bipartisan solution than many people realize. In the last presidential election, both Clinton and Bush set the stage by endorsing managed competition in health reform. Just this week, our Nation's 50 Governors unanimously endorsed managed competition. Now it is Congress's turn.

I am proud of the fact that our bill is almost identical to the Governors' views. What the Governors found this week is what we discovered some 3 years ago; through two Congresses, our bill is still the only bipartisan health care reform approach. Health care may be a giant \$930 billion issue, it may be 14 percent of the GNP, but the bipartisan middle ground in this debate may be 1 inch wide.

What is managed competition and how has it broken the partisan gridlock on health reform? Managed competition is an approach designed by the so-called Jackson Hole Group. I wish that Dr. Alain Enthoven could be with us today on the following panel, but I understand that his mother fell and broke her hip, and he is not able to be with us.

We basically took the Jackson Hole approach and modified it, consulted with hundreds and hundreds of our folks back home—regular people as well as with health care experts—and we consulted with American Health Care Systems, a not-for-profit hospital chain, as we put together our bill.

Managed competition is an approach that is being field-tested already in various forms in Minnesota, California, Florida and Washington State, as well as in 150 American cities. Versions of managed competition have already been working for years in places like Memphis, Tenn.; Cincinnati, Ohio; Rochester, N.Y.; Orlando, Fla.; and countless other cities around the country. Nine million Federal employees today are benefiting from an early type of managed competition that has been in place for over 30 years.

Managed competition has broken partisan gridlock by combining the best features of managed competition and government regulation. This is not a new entitlement program; this is an empowerment program. This is not the old please-the-bureaucrat regulatory paradigm. This is a new please-the-patient, please-the-customer regulatory paradigm.

Managed competition means that every American should be able to shop for health care. That may sound unremarkable, but we have never been allowed to shop for care. We have never been able to know the price or quality of care in advance. We have never been empowered to be able to get the best deals from health providers or health insurance companies.

Now, for the first time, we will have the power and the information to choose the best plan for ourselves and our families.

We like the idea of annual, menu-based shopping for health coverage, similar to the system that Federal employees have enjoyed for years. Instead of Congress keeping a benefit system to itself and its employees, it is high time we shared that system with the American people.



We think that if done properly, managed competition will enhance consumer choice, promote higher medical quality and contain costs. In fact, managed competition, we feel, is tougher and fairer on costs than any government price control program could ever be.

We support health insurance reforms like those in the Clinton plan. We make sure that every American can get good health insurance at low group rates, as if they worked for the biggest company in town. No insurance company would be able to turn you down anymore. People would be able to get and keep insurance no matter what happens to them, no matter how sick they are, where they work, no matter if they are between jobs.

In health care jargon, we are for guaranteed issue insurance, with a ban on preexisting-condition limitations and experience-rating—no more cancelled policies, no more price gouging, no more insurance company discrimination.

We not only make insurance available, we make it affordable. Every American under 200 percent of poverty, double the poverty level, would qualify for help from the program that would replace the current Medicaid program. That means that four times more people in our country would be covered than under the current Medicaid program.

Little attention has been paid to the fact that every taxpayer in America could benefit from a new tax deduction in our bill for low-cost, basic health coverage. Today, in our Nation's third largest health program, only corporations can fully deduct. The Clinton plan would give the self-employed a full deduction, but not the employee. We want not only the self-employed, but also the regular employee to be able to deduct. This alone is a \$54 billion program over the next 5 years to help average Americans better afford health coverage. This is effectively a middle class tax cut, paid for by trimming a corporate tax break.

These reforms should remove all obstacles to health insurance coverage for all Americans. There is no reason why everyone wouldn't be able to be covered under these reforms. If there are some, we will soon know who they are and we will be able to cover them under the President's timetable, which is 1998. No other bill in Congress comes this close to meeting the President's demands that "We guarantee every American private health insurance that can never be taken away."

The McDermott bill does not even allow private health insurance. The Chafee bill does not promise coverage until the year 2005, and then it is highly conditional on a pay-as-you-save basis.

When you look at a broad range of health issues, you will also discover that our bill is the closest bill in Congress to the President's bill. There are many similarities, but there are also some key differences. We agree on most of the goals of health reform, but we disagree primarily on the role of government involvement.

The administration bill usually relies on a big government approach; we prefer a small government approach. We disagree with the employer mandate, with the bureaucratic price controls, with large and regulatory health alliances, with politicalization of the basic benefits package and excessive State flexibility. I would be happy to go into these and other issues in whatever detail the subcommittee would like.

Our bill does promise less than the administration's bill, but we are confident that we can deliver on those promises. The administration bill contains at least four new entitlement programs and pays for a number of them by cutting the rate of growth of Medicare by \$124 billion over the next 5 years. Will seniors approve of this trade? I don't know.

To conclude, Mr. Chairman, our bill is closer to the President's and closer to the Governors' recommendations than any other bill. Ours is the only bipartisan bill. It is certainly far from perfect, but it is the best starting point to achieve national consensus on this complex issue.

With managed competition, we have an opportunity not to copy other nations, but to beat other nations. I hope that we will rise to that challenge.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you.

[Testimony resumes on p. 27.]

[The documents referred to by Mr. Cooper follow:]



## KEY ELEMENTS OF MANAGED COMPETITION

### Insurance and Delivery System Reform

If costs are to be controlled, the government must encourage the market to fundamentally restructure the way health care is provided. In today's market, few providers have strong incentives to hold down costs: The more services they provide, the more they can bill insurance companies, and the more they are paid. Providers are not accountable for what they charge, and they are not accountable for medical outcomes.

**Managed Competition Act:** Through changes in the tax code, the bill strongly encourages providers and insurance companies to form Accountable Health Plans (AHPs) — improved and expanded versions of today's Health Maintenance Organizations, Preferred Provider Organizations, other group practices, and even traditional fee-for-service insurance. AHPs will be organized to compete on the basis of offering high-quality, low-cost care, and will offer insurance and health care as a single product. They will be responsible for looking after the total health of individuals.

AHPs will have to price their plans in a dramatically different way than they are priced today. In our current system, health plans can "cherry-pick" the healthiest individuals, and deny coverage or charge extremely high rates for others. Plans can also deny coverage for individuals with pre-existing medical conditions. Under our proposal, any plan engaging in those practices will lose its tax-favored status.

- AHPs must offer a standard package of federally-defined uniform, effective health benefits. They may offer more comprehensive plans, but employers and individuals who purchase those plans will receive a tax break only for the least costly package of standard benefits. AHPs must require copayments for medical services, except for preventive care.
- AHPs must require all of their providers to report the medical outcomes of their patients in accordance with federal guidelines.
- AHPs will not be allowed to vary premiums based on how sick people have been and how many claims they have had in the past. AHPs will be allowed to vary premiums based only on geographic location, and to a limited degree based on age.
- AHP plans must enroll all individuals who apply for coverage (open enrollment), and will not be allowed to deny coverage for pre-existing medical conditions.
- State mandates on benefits and state restrictions on managed care are preempted.
- An AHP may be set up by a very large business to provide coverage for its employees. It must meet all of the above rules, except for the requirement of open enrollment.

### Enhancing Small Business and Individual Purchasing Power

Compared with large businesses, small businesses and individuals face two major disadvantages that discourage them from purchasing health coverage:

- As much as 40% of the premiums paid by small businesses and individuals goes toward administrative costs of health insurance (compared with less than 10% for large businesses).

- Small businesses do not have enough employees to spread the risk of insurance around. If even one employee has high medical expenses, insurance can quickly become unaffordable. The problem is even worse for individuals.

**Managed Competition Act:** To make health coverage more available, all individuals and small businesses will have access to coverage through a Health Plan Purchasing Cooperative (HPPC):

- HPPCs will be state chartered, not-for-profit cooperatives, with exclusive geographic territory (i.e. there will be one HPPC per region). States will have the option of establishing more than one HPPC in a state (e.g. one in a metropolitan area and one for the rest of the state).

- All employers with fewer than 100 employees will be able to purchase coverage through their local HPPC. States will have the flexibility to choose a threshold higher than 100, so long as no more than half of all employees in a state purchase through a HPPC (around 500 employees in most states). Individuals also will have direct access to all health plans in their area through the HPPC.

- HPPCs will offer a menu of accountable health plans, including clear, standardized information for each plan on its price, an aggregate measure of the quality of care it provides and its level of enrollee satisfaction. Each individual (not their employer) will choose the health plan he or she prefers and will be able to change plans once a year.

- HPPCs will collect all individual and small business employee premiums and distribute them to the accountable health plans. Using a federal risk-adjustment procedure, HPPCs will pay more to AHPs which have enrolled high-risk individuals and will reduce payment to AHPs which have enrolled low-risk individuals.

- HPPCs will eliminate the burden of COBRA health plan continuation coverage for businesses. If an individual loses his job, he can remain in the HPPC and pay premiums himself.

- HPPC administrative expenses will be financed by a small surcharge (less than 1%) on premiums which should be dramatically less than today's administrative charges.

## **Tax Fairness Under Managed Competition**

Current law provides two tax benefits for the purchase of health insurance:

- Most businesses are allowed to deduct the full cost of any health coverage they provide to their employees. This deduction is allowed for any kind of health plan, without limit.

- Individuals may exclude from their income any amount their employer pays toward health coverage. Like the business deduction, this tax exclusion is available for any kind of health plan policy with no dollar limit.

The federal revenue loss associated with these tax provisions exceeds \$65 billion a year, making it the third largest federal health program after Medicare and Medicaid. And



because these tax benefits grow with greater health care spending, they contribute to health inflation.

In addition, these benefits are not equitably distributed. Self-employed individuals are allowed to deduct only 25% of the cost of health benefits. And individuals who buy coverage on their own get no tax benefit unless their health expenses exceed 7.5 percent of their income. *As a result, families earning more than \$100,000 receive, on average, almost 30 times as much tax benefit as those with incomes of \$10,000.*

**Managed Competition Act:** To encourage health plans to offer standard benefit plans so consumers can shop on the basis of price and quality, and to discourage inflationary "Rolls-Royce" health policies, which don't control costs, the bill caps tax deductibility at the cost of the lowest-price AHP plan meeting minimum federal standards in the area. Subject to this cap:

- Tax deductibility for the self-employed is increased to 100% of their AHP premium.
- Individuals who pay all or part of an AHP premium would be able to fully deduct their payments.
- If an individual or employer purchases coverage from a plan which is not a federally-qualified AHP, none of the amount paid is deductible.

## Market Oversight and Accountability

Managed competition will work only if the market is carefully overseen and AHPs are held publicly accountable for how they provide.

**Managed Competition Act:** An independent Health Care Standards Commission will oversee the health market, much like the Securities and Exchange Commission oversees the financial market.

- The Commission will:
  - Establish and update the standard health benefits package, which must include the full range of medically-appropriate treatments and preventive services
  - Establish standards for reporting costs, health outcomes, and measures of consumer satisfaction
  - Develop factors for risk adjustment of AHP premiums
- The Commission will function independently. Its recommendations on the basic benefits will be submitted to Congress and will have to be approved or rejected on an up-or-down vote.
- The Commission will be advised by expert private sector boards which advise on benefits and health plan standards (this will be done in much the same way that the Accounting Standards Board advises the SEC).

## Consumer Information

Accountable Health Plans will be required to report full information on the outcomes of treatments and the costs of their plans. Such information will include:

- Process measures, such as the percent of enrollees receiving immunizations,

- mammograms, cesarean deliveries, etc.
- Outcomes measures, such as the proportion of patients who died, had complications, fully recovered, etc.
- Patient satisfaction

This information will be given to consumers and employers to allow them to choose the most efficient, highest-quality health plans. It will also be used by providers to help them change their practice styles. This new accountability is fundamentally different from the current practices of some managed-care groups, where doctors are second-guessed on a case-by-case basis.

## Low-Income Assistance

Medicaid is the main program providing health services to the poor. The program is financed by both the federal government and the states, and covers both acute care (e.g. hospitals and physicians) and long-term care (e.g. nursing homes and home health care).

Medicaid has a complicated set of requirements for eligibility, and today covers fewer than half of the people below the poverty line. The shared responsibility for financing has bred irresponsibility on the part of the states and the Federal government.

**Managed Competition Act:** Medicaid is replaced with a new federal program which will help purchase coverage from AHPs for low-income individuals:

- All individuals and families with incomes below 200% of their state's poverty level will be members of a HPPC and will receive federal assistance for premiums and copayments. Eligibility for this new program will be separated from eligibility for welfare.

- Individuals and families with incomes below 100% of poverty will be eligible to join an AHP with no premium cost to them, and with nominal copayments. They will also receive assistance for certain items (e.g. eyeglasses or hearing aids) which might not be covered by the basic benefit package offered by AHPs.

- Individuals and families with incomes between 100% and 200% of poverty will be eligible to join an AHP, and will be responsible for paying a portion of the premium, based on a sliding scale. They will also have nominal copayments.

- Medicaid will be repealed, freeing up substantial state funds. The states will gradually assume responsibility for long-term care, with greater flexibility to try innovative approaches.

## Access in Rural and Other Underserved Areas

In order to foster competition in rural and underserved areas, HPPCs will have special tools to attract health plans and health care providers. The bill also creates new AHP development grants and a technical assistance program to encourage the creation of AHPs in these areas. New funding will also be made available for Community and Migrant Health Centers and Rural Health Clinics to help them transition into the new system.

A new title on medical education will promote the training of more primary care physicians and will increase funding for training mid-level practitioners, the National Health Service Corps and Area Health Education Centers.



## Expansion of Preventive Health Services

Greater use of preventive care is key to health care cost-containment and a healthier nation. The bill encourages preventive care in a number of ways:

- Because they will be offering insurance and health care as one product, AHPs will have a strong financial incentive to keep their enrollees healthy.
- Preventive health care will be the only service for which no co-payment or deductible may be charged.
- The bill provides significantly increased funding for a variety of existing preventive health initiatives, including immunization programs, lead poisoning prevention, breast and cervical cancer screening, and early AIDS intervention. Increased funding will also be provided for the Office of Disease Prevention and Health Promotion and the Office of Smoking and Health.
- In addition, preventive services available under Medicare will be expanded to include annual mammography, certain immunizations and colorectal screening.

## Malpractice Reform

Unnecessary litigation and defensive medicine have contributed to rising medical costs, and must be controlled as part of health care reform. In some regions of the country the high cost of liability insurance has not just driven up costs, but has reduced access to care, especially for high-risk services like obstetrics.

The bill makes substantial changes in the law, including limiting non-economic damages and reducing unreasonably long statutes of limitations. It supersedes state laws, except where they are more stringent than federal law. These changes will be combined with new efforts by AHPs to identify sub-standard providers.

## Paperwork Reduction and Administrative Simplification

At least \$5 billion in annual health care expenditures could be saved by reducing paperwork required by the nation's 1,500 insurance companies with their multitudinous forms. The bill would establish national goals for health plans to achieve efficiencies: standardize claims forms and electronic transmission of data. The National Health Board will have the responsibility and authority to ensure that these goals are met.

## Financing

Current Federal Medicaid spending is redirected to fund the new program. In addition, the Congressional Budget Office has estimated that the bill requires roughly \$25 billion in new Federal spending annually. This is financed by: capping employer deductibility of health benefits (\$16 billion); reducing the increase in provider fees under Medicare (\$2 billion); phasing out the Medicare Part B premium subsidy for upper-income beneficiaries (\$3 billion); and prefunding federal retiree health benefits (\$1 billion).

October 7 1993

## The Managed Competition Act of 1993

### *Questions and Answers*

**Q: How does the Managed Competition Act (MCA) guarantee access to health care for all Americans?**

**A:** The MCA makes health care coverage available and affordable for all:

- \* Health plans will be prohibited from refusing to cover anyone; excluding coverage for pre-existing medical conditions; or charging higher premiums to those with bad medical histories.
- \* All Americans will be able to enroll in the health plan of their choice through their local purchasing cooperative or their employer.
- \* A new tax deduction will reduce the cost of health care by about one-fourth for everyone whose employer does not pay for coverage.
- \* Enrollment in a qualified health plan will be free for everyone under the federal poverty line and subsidized for everyone up to 200% of poverty.
- \* Health plans will be given strong incentives to locate in rural and urban underserved areas.

**Q: Don't you need an employer mandate to reach universal coverage?**

**A:** The MCA guarantees universal access to health coverage, a significant achievement by any standard. Universal coverage -- a goal shared by all MCA cosponsors -- is much more difficult to achieve. Hawaii's experience with an employer mandate has shown that it alone will not guarantee universal coverage. According to the Census Bureau, approximately one-third of the uninsured have no connection with the workforce. A mandate on individuals, in theory, would reach everyone and would not have a negative effect on jobs, however it is likely to be difficult to enforce. Our priority must be to reform the system so that everyone feels it is to their benefit to participate voluntarily. If a mandate is necessary, it should be imposed after the system is reformed.

**Q: How does the Managed Competition Act control costs?**

**A:** The MCA addresses the causes of health care inflation, not just the symptoms:

- \* Requiring health plans to cover the health needs of their enrollees for a pre-paid premium will promote cost-effective care. Plans will have a financial incentive to eliminate inappropriate and unnecessary care, administrative waste and inefficiency. Prevention will be encouraged.
- \* The one-stop-shopping menu and standardized benefits packages make it easier for consumers to shop for health plans on the basis of price. Health plans will reap greater marketplace rewards for keeping their premiums low.
- \* A limit on the tax deductibility of health benefits makes consumers more cost-conscious.
- \* Group purchasing through a HPPC will dramatically reduce the share of administrative costs for individuals and small employers which runs at 40% of premiums today.
- \* Malpractice reforms will reduce defensive medicine and lower malpractice premiums for providers.
- \* Administrative simplification will reduce paperwork.



### Managed Competition and Individuals

**Q: How will buying health care change for individuals?**

A: Individuals will choose once a year from a menu of health plans. They will have information to compare plans based on price, quality and patient satisfaction. All other differences among plans like deductibles, copayments, and benefit packages will be standard so that individuals can make direct value for money comparisons. For the first time, individuals who purchase their own health coverage would be able to deduct the cost from their taxable income.

**Q: Will consumers be able to choose their own physician?**

A: Yes, if they choose such a plan that offers a choice of physicians. Many health plans, like preferred provider organizations and point-of-service plans, offer provider choices both inside and outside their networks. Some HMOs do not offer such choices.

**Q: What benefits will be included in the standard benefits package?**

A: The benefits package will be developed by the Health Care Standards Commission with the advice of a private sector panel of experts. It will then be sent to Congress for consideration using "base-closing" procedures (i.e. up or down vote, no amendments). It will be based on a list of treatable diagnoses rather than an entitlement to a certain amount or kind of care. For example, the benefits package would not specify whether chiropractic services were covered or not. It would be up to the health plan to determine when chiropractors were the most effective and efficient provider for certain diagnoses.

The benefits package would similarly not specify an arbitrary limit on the number of inpatient mental health care days. This kind of benefits package has too often led to abuse by providers with little regard to the effect on the individual by the insurance companies.

**Q: How will individuals in rural areas be affected?**

A: Because of the demographics of rural areas, they in particular will benefit from insurance reforms, group purchasing and expanded assistance to the poor. The MCA includes additional measures for rural and urban underserved areas including: access requirements for AHPs; technical assistance and grants for AHP development; and increased funding for programs designed to attract health care providers. States are given flexibility to design special approaches for chronically underserved areas.

### Tax Reform

**Q: How does the Managed Competition Act change the tax treatment of health benefits?**

A: Employers would no longer be able to receive a tax subsidy for wasteful or excessive health spending. Their deductibility for health benefits would be limited to the cost of the least expensive plan in the area offering the standard benefits package. Unless spending above the most efficiently-delivered package of benefits is in after-tax dollars, incentives for cost-containment will be muted.

**Q: What would prevent the least expensive plan from being the worst quality plan?**

A: Generally, the best quality care is not the most expensive. For example, the Mayo Clinic has one of the lowest priced health plans in the country even though it is considered one of the best providers of care in the world. They are less expensive because they are

more efficient. Preventive care, early intervention, prompt diagnosis and appropriate, effective treatment are all indicators of high-quality care and lower cost care.

Nevertheless, the health plan setting the limit on deductibility would have to meet minimum quality standards and enrollment requirements set by the Health Care Standards Commission.

**Q: Would employees' health benefits be taxed?**

A: No. The current exclusion from income of employer-provided health benefits would not be limited. Furthermore, individuals who pay all or part of their insurance premiums would be able to deduct that cost.

Low-Income Assistance

**Q: How much would a two parent family with two children and an income of \$20,000 per year have to pay for a health plan?**

A: They would pay about \$144 per month for the entire family. The government would pay 57 percent of the cost or \$191 per month.

**Q: How about a single parent with two children making \$15,000?**

A: They would pay about \$100 per month. The government would pay 70 percent of the cost or \$235 per month.

**Q: What if a family can't afford the out-of-pocket expenses?**

A: Low-income individuals would receive assistance with out-of-pocket expenses, but everyone would still have to pay something, even if a token amount. Preventative care would be exempted from copayments and deductibles.

Effect of Managed Competition on Providers

**Q: Will Accountable Health Plans (AHP) be HMOs?**

A: Some of them will resemble today's HMOs, but AHPs will take all forms, just as health plans do today. AHPs can be HMOs, PPOs, fee-for-service or any other type of plan. The main differences between AHPs and today's health plans is that all AHPs will be required to offer coverage to everyone at non-discriminatory rates, offer the standard package of benefits, and report on the quality of their care. Within those requirements, the market will decide what kind of AHP will work the best.

**Q: What will physicians and hospitals have to do to adapt to managed competition?**

A: Providers will have to change dramatically the way they look at patients. Rather than treating symptoms, they will have to treat the whole patient. The measurement of health outcomes will cause providers to examine, for example, the extent to which stress and depression might be slowing the recovery from a serious illness.

Providers will be constantly challenged to improve their practice of medicine so that it improves the functioning of the patient. For example, by collecting data from follow-up visits, a physician in Portland, Oregon found that a high tech ceramic coating designed to speed bonding of artificial hips to patient's bones is not worth the potential bone erosion and the extra cost (Fortune, March 23, 1992).



Managed Competition and Employers**Q: How will small businesses provide health plans?**

A: Small business (those with fewer than 100 employees) will be members of local purchasing groups called Health Plan Purchasing Cooperatives (HPPCs). HPPCs will offer a choice among all AHPs in the area. HPPCs will give small businesses the buying power, lower administrative costs and risk sharing of large businesses. For a company of fewer than five employees, 40% of the health care premiums go to administrative expenses compared with roughly 5% for large businesses (Congressional Research Service).

**Q: Aren't HPPCs a monopoly?**

A: HPPCs are like a farmer's market where all the farmers come to sell their products. Each HPPC will be governed by the individuals and small businesses for which it purchases and will be required to offer all health plans so that no single health plan gained a monopoly.

**Q: How will large company ERISA plans be affected?**

A: ERISA plans could continue to self-insure and be exempt from state mandates, but only if they offer the standard benefits package and comply with the outcomes reporting and other AHP requirements (except the requirement of open enrollment). They would also be subject to the tax deduction limit of the least costly plan in the area.

October 6, 1993

## Comparison of Managed Competition Act and Administration Plan

### SIMILARITIES

#### Both plans:

- guarantee universal access to health insurance
- subsidize individuals' purchase of coverage based on their income
- require health plans to offer coverage to everyone and prohibit them from denying coverage for pre-existing medical conditions
- promote competition among health plans to reduce the increase in health care spending
- establish regional purchasing groups through which individuals and small businesses purchase coverage
- establish a standardized benefits package to be offered by health plans
- provide for individuals to choose their health plan, not their employers
- require health plans and providers to report on the quality of their care (health outcomes) and enrollee satisfaction with their care
- allow the self-employed to deduct the cost of health insurance
- provide incentives to develop community-based health plans in rural and urban underserved areas
- reform funding of graduate medical education in order to promote the training of more primary care physicians
- encourage preventive care
- preempt state anti-managed care laws
- encourage the utilization of non-physician providers
- promote administrative simplification, standard claims form and electronic claims processing

## DIFFERENCES

**Employer Mandate:** The Clinton plan would require employers to pay 80% of their employees' health premiums. The Managed Competition Act (MCA) would not require employers to pay for employee's health costs.

**Premium/Price Controls:** The Clinton plan includes alliance-by-alliance caps on premiums for managed care plans and provider price controls for fee-for-service plans. The MCA does not contain a global budget, caps on insurance premiums, provider fee schedules or any other artificial constraints on private sector health care spending.

**Cost:** The MCA costs about \$25 billion a year compared with about \$70 billion a year in new federal spending and as much as \$30 billion in mandated new employer spending under the Clinton plan.

**Nature of Purchasing Cooperatives:** The MCA's Health Plan Purchasing Cooperatives (HPPCs) are governed by their members (i.e. individuals and employers in the area). HPPCs are non-regulatory bodies which must offer to their members all health plans in the area. States choose the employer size for purchasing through the HPPC from between 100 and roughly 500 employees. Larger employers could not opt into the HPPC. The Clinton plan's Health Alliances can be state government agencies with the authority to exclude health plans. Employers with fewer than 5,000 employees are required to purchase through the regional Alliance; larger employers are encouraged to opt in.

**Tax Deductibility of Health Benefits:** The MCA caps employer deductibility of health benefits at the cost of the lowest-priced plan offering the standard benefits package and meeting quality and enrollment standards. Deductibility is extended to individuals subject to the same cap. The Clinton plan limits the employee's tax exclusion to any amount spent on the standard package of benefits; however any benefits currently provided beyond the standard package would be exempt from this limit for ten years.

**New Entitlement Spending:** The Clinton plan would significantly increase entitlement spending through new and existing programs (e.g. financing retiree premiums, establishing business subsidies and expanding Medicare benefits). The MCA acknowledges the desirability of some of these new benefits but requires that they be extended only on a pay-as-you-go basis.

**Malpractice Reform:** In addition to various other malpractice reforms, the MCA would provide for caps on non-economic damages (i.e. pain and suffering) in malpractice awards. The Clinton plan does not limit non-economic damage awards.

**State Flexibility:** The MCA allows state flexibility within the context of nationwide market-based reform. The Clinton plan would allow any state to establish a Canadian-style single-payor system.



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January 18, 1994

Robert Reischauer, Ph.D  
Director, The Congressional Budget Office  
Congress of the United States  
Washington, DC 20515

Dear Bob:

This letter responds to the recent CBO document "Behavioral Assumptions for Estimating the Effects of Health Care Proposals" (November 1993), and to CBO estimates that managed competition would not appreciably reduce health care costs. It makes four main points:

**I. CBO has made an important error in interpreting the research it cites on the premium price elasticity of demand of health plan choice, an error that makes all the difference between whether markets can or cannot discipline prices. The error may have led CBO to the wrong conclusion.**

Consider an illustrative example. HMO A charges a premium of \$100 per month. Employers in its area contribute \$90. HMO A decides to cut price by \$1.00. The result in the next open season is a 6 percent increase in the HMO's membership. What does that imply about the price elasticity of HMO A's demand curve?

The CBO answer is that a 10 percent price cut (as seen by the consumer) produces a 6 percent increase in membership. Therefore, HMO A's demand curve elasticity at this point is an inelastic  $-0.6$ . In that case, of course, HMO A would have no incentive to reduce price. The contrary would be the case. The market would not drive it to reduce cost and price.

On the other hand, the answers of Bryan Dowd, Roger Feldman and W. Pete Welch [1], [2] - the authors whose work is cited in the CBO document in Table 3, page 10 - and my answer, would be that a 1 percent price reduction (as seen by the HMO, i.e., the price-maker) produced a 6 percent increase in membership. Therefore, HMO A's demand curve - the one relevant to its price-

making decision - is an elastic -6.0, ten times greater. In that case, depending on its marginal cost, HMO A's reward for cutting price is likely to be a whole lot stronger. If HMO A started with 100 members, the \$1 price cut would increase membership to 106 and total revenue from \$10,000 to \$10,494.

Bryan, Roger and Pete explained this point in their articles. The econometrics were done using the consumer out-of-pocket price only. But the correct inference regarding the relevant demand elasticity for price determination must be based on the HMO's total price. In a letter to Sandra Christensen (copy enclosed), Bryan and Roger conclude CBO understated the elasticities they found by a factor of 16.5. Pete's article explained the same point, and he estimated employer contributions averaged about 90 percent of premium. Thus, CBO underestimated the elasticity implied by his findings by a factor of 10.

Though these much greater elasticities may not make intuitive sense to people who observe today's marketplace, the discrepancy can be explained by the fact that, because of common employer practices and the tax code, most people do not face a situation in which they must pay a full dollar more out of pocket if they choose a health plan that costs a dollar more. Of course, under managed competition they would.

The significance of this difference in price elasticity is not merely the numbers of people who would switch to HMOs. Experience in competitive situations suggests that very high percentages of people would switch in order to save money, if they get to keep the savings. CalPERS beneficiaries are now 80 percent in HMOs; most of the rest are in geographic areas not yet served by HMOs. We think that with adequate incentives, HMOs will expand into these areas. At Stanford this year, we became 100 percent HMO (one with a point-of-service option) for all employees living in the local area.

**The main significance of the high elasticity of demand is that a price competitive environment would motivate Accountable Health Plans to reduce cost over the long run.**

There is much such organizations can do to cut cost while maintaining or improving quality: study variations in practice patterns from the point of view of cost and outcomes and adopt the least costly way of producing the best outcome; match numbers and types of doctors and other resources to the needs of the population served; concentrate costly complex procedures like open heart surgery in high-volume regional centers; substitute less costly personnel for routine tasks within their competence; and practice continuous quality improvement along the lines practiced by Xerox and Hewlett Packard.

Studies of the savings that have been generated by HMOs, such as the 28 percent reduction in resource use by Group Health Cooperative of Puget Sound, compared to fee-for-service in the RAND study, are not an adequate indicator of what could be done over time in a price-competitive environment because, to date, HMOs have not had to operate in such an environment. But experience in other high-tech industries shows that competition over quality and price can motivate large cost reductions.

CBO's error could explain why CBO reached the conclusion that the Managed Competition Act of 1992 would not reduce health care costs appreciably. Since the issue was the efficacy of market forces, which turn decisively on demand and supply elasticities, I assume these understated demand elasticities were factored into the CBO model.

**II. CBO's use of studies based on 1982 and 1984 data impart a substantial downward bias in the estimated price elasticity of demand, and gives us, at best, a lower bound estimate of what price elasticity would likely be today.**

The Welch study - a pathbreaker for its time - used 1982 BLS data, when there were 10.8 million HMO members as opposed to today's 45 million. That makes a large difference because the presence of competing HMOs, i.e., close substitutes, increases the price elasticity of each HMO's demand curve. Furthermore, greater familiarity with and market acceptance of HMOs that has occurred since 1982 would raise price elasticity. Moreover, because of data limitations, Welch was limited to examining the elasticities between conventional plans and the largest prepaid group practice in each market, and not the multiple HMO situations that characterize most metropolitan areas. Yet, again, the presence of multiple HMOs increases each HMO's price elasticity of demand.

**III. Managed competition as proposed by the Jackson Hole Group,[4] and largely adopted by Cooper-Grandy, and by Clinton, proposes to generalize a set of elasticity-enhancing measures, that have been applied successfully in local situations, to the whole health care economy. Somehow you should take account of that in your estimates.**

Here are the proposed general principles and procedures:

1. Everybody participates in an annual "open season" enrollment in which, at a single time and place, they have all alternatives presented to them for choice, with accurate and binding information on price.



2. Virtually everyone is in an Accountable Health Plan, so choice of managed care plan becomes the norm, and plans become closer substitutes.
3. Full subscriber responsibility for premium price differences, as applied at Stanford, recently adopted by the University of California, in place since 1986 for Minnesota State employees, etc. Employers required to make level dollar defined contributions, as in the Clinton plan.
4. Limit on tax-free employer contributions set at the price of the low-priced qualified plan in the region, so subscribers pay premium differences with after-tax dollars.
5. Standardize the benefits package to facilitate value comparison, prevent product differentiation and market segmentation, and to prevent fear of "air pockets" or hidden gaps in coverage from deterring decisions to change plans.
6. Risk adjust premiums, at least by demographic variables.
7. Individual choice (vs. group choice) of plan so those who are willing to change doctors and plans to save money can do so even if co-workers are not.
8. Systematic production of information on consumer experience and quality of care in all plans.

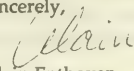
I described all this in some detail, *inter alia*, in two articles in *Health Affairs* in 1993. [5],[6]

All of these measures have been demonstrated in pieces around the country. The proposed policy is to put it all together in a coherent program. The combined effect of all these measures is very likely to be a large increase in price elasticity of demand compared to the 1982 and 1984 results.

**IV. The combined effect of more and larger HMOs and similar managed care plans, greater market acceptance, and managed competition is difficult to estimate. We are talking about new terrain. There is uncertainty, just as there is uncertainty about the true efficacy of President Clinton's proposed premium price controls. The best way for CBO to handle this is honestly to admit that there are large uncertainties in both cases, and perhaps to handle the elasticity issue parametrically, giving us a range of estimates following from a range of assumptions.**

I suggest you begin with a 16.5-fold increase in the Dowd and Feldman results, a 10-fold increase in the Welch estimates as recommended by the authors. Then test the effect of some substantially greater elasticities to reflect changed market conditions and the measures of managed competition. Re-run your models with these modified assumptions. If your models are robust, new runs should show the significant cost-reducing effects of competition.

Best wishes.

Sincerely,  
  
 Alain Enthoven

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Mr. WAXMAN. Mr. Grandy.

**STATEMENT OF HON. FRED GRANDY, A REPRESENTATIVE IN  
CONGRESS FROM THE STATE OF IOWA**

Mr. GRANDY. Thank you, Mr. Chairman.

Let me echo the accolades my colleague from Tennessee has given you in helping shape this debate and kicking off the proceedings today, which I hope will be a long debate.

I heard the President yesterday, when he was addressing the American Hospital Association, talk about how complicated this issue is, particularly for people that are not materially involved the way lawmakers are. I couldn't agree more with that. That is why I hope, as we begin what I hope will be an exhaustive and informative number of hearings, we rely more on substance than sniper fire as we begin to try to frame these issues.

With that in mind, I would like to offer with my testimony today an editorial in today's Washington Post by Robert J. Samuelson, which is entitled "The Dishonest (and Nasty) Health Debate." I ask unanimous consent to insert this in the record.

Mr. WAXMAN. Without objection, we will receive that.

Mr. GRANDY. I would like to just read one paragraph of this, because I think it serves to set what I hope will be the tone of this deliberation.

Mr. Samuelson says, "Both Clinton and his critics skirt the real problem. Most Americans expect far more from the medical system than it can deliver. In general, we think people should have good care when they need it. Costs should be no bar, insurance should pay. The issue is a moral one, but naturally we don't want soaring insurance costs to raise our taxes or depress our salaries. All of these are worthy goals—but, unfortunately, contradictory ones."

That has led to, I think, in the public's mind a national consensus on health care debate, which we as lawmakers are now going to have to wrestle with. Whatever congressional district you are in, you are probably going home and hearing your general public say, "I don't know what I want on health care," and, "I want it now."

That leads to another conclusion that doesn't give us much comfort as we try to frame some solution at the Federal level. You can pretty much conclude that when it comes to a national consensus, people are all for health care reform as long as they don't have to change anything. That is exactly what we are trying to do in this particular debate and with the series of proposals. I want to say, though, that no matter what we do, the status quo is not on the table. We will not remain with what we have.

Critics of the President's plan believe that there is no health care crisis. I think we have come too far to agree that we need only to tinker at the margins. But I want to say and echo what Jim Cooper said. The Cooper-Grandy bill, although it differs from the administration bill on the means to the end, does believe in guaranteed universal coverage at a date certain; and I see the differences now more as a border skirmish than a war.

With that in mind, I think it is unfortunate that we see articles in today's New York Times and today's Wall Street Journal saying White House Lobbies Strongly to Block Business Support of Rival



## Health Plan, Clinton's Campaigning to Scuttle Endorsement of Rival Health Plan.

Mr. Chairman, this is not a rival health plan. This is a companion piece to achieve a goal. The only reason that Mr. Cooper and I are allying our forces is because we believe strongly that when it comes to health care reform, if you want to control costs; if you want to improve access; if you want to maintain quality in what is arguably the best quality medicine in the world; if you want to solve what I call the "value equation," which is quality plus access plus cost-containment, must equal value or the American people simply won't buy it, then you have to rely on the strength of our Nation, which is markets.

Markets can say no, Mr. Chairman; governments cannot.

The Cooper-Grandy bill at its core basically premises that when it comes to regulating health care, controlling costs and providing access, markets should go first before mandates and monopolies kick in. That is the central point that I want to make.

I want to go now to a criticism that has been leveled against the Cooper-Grandy bill that we do not provide for universal coverage in our proposal. I don't agree with that. In fact, universal coverage is a goal that Mr. Cooper and I share, and we believe that the universal access mechanism in Cooper-Grandy is the best means of achieving universal coverage.

The whole discussion of access versus coverage is really, I think, an issue of semantics. Access is a means to the end of coverage. It is really more a discussion of timetables and how we get to universal coverage. As I said earlier, Mr. Cooper and I use a different mechanism than the administration to achieve universal coverage because we trust markets to do the job for us.

Picking up on Mr. Klug's point, the one State in the Union with an employer mandate for 20 years is Hawaii. They have not achieved universal coverage. They have only 88 percent of their population covered. That is with an employer mandate.

In this country, right now we have 85 percent of our population covered with a voluntary employer contribution to health care. We have to ask ourselves whether or not the market isn't telling us something there.

I came here to offer my aid, along with Mr. Cooper, in achieving our shared goal of ensuring all Americans a system of health care that provides the quality of care Americans want and deserve and will take the responsibility to acquire. This debate too often becomes an argument against right versus responsibility in health care. We both agree and many of the people not cosponsors of this bill agree that health care solutions must split the difference between right and responsibility.

Having said that, let me go to some of the points in this bill that I think are worth mentioning. In many of these places, these are not points that divide; they are themes that unite.

Specific components of the Cooper-Grandy bill include insurance reforms to encourage insurers and providers to combine and form accountable plans. Accountable health plans will not be allowed to exclude coverage of preexisting conditions and will not be allowed to charge higher rates based on an individual's medical history. In

other words, the days of experience-rating are almost certainly over, no matter what theme we adopt for health care.

Access provisions, which will ensure individuals and small businesses affordable coverage by joining health plan purchasing cooperatives. These cooperatives will offer group rates with lower administrative costs. Once a year individuals will be able to choose from a menu of AHP's in the area, much like the Federal Employee Health Benefit system. Again, why not give small employers, those people in our workplace that have the hardest time providing the benefits that they would like to provide to remain competitive, the same advantages that you have if you work for the Federal Government? Provisions to change the incentives in the system from "more money for more services"—in other words, fee-for-service—to a system in which health plans are prepaid so they will have incentives to promote preventive care, which eliminates unnecessary tests and ineffective treatments and which reduces administrative costs.

Obviously, one of the successes of managed competition around the country is now conditioned behavior among the general public to purchase health care and not just insurance. The consumer becomes more materially involved in the product they are buying. Right now, the average consumer probably spends more time pricing a car stereo than he would a package of health insurance.

A Federal, low-income assistance program will pay a health plan premium for all people below 100 percent of the poverty level. Individuals between 100 percent and 200 percent of the poverty level will receive sliding scale subsidies toward the purchase of a health plan. In other words, the neediest victims in that great supposedly homogeneous population of 37 million Americans that are without health care—which we all know is somewhat of a bogus number, because they are not all disadvantaged by the system—but the people that are disadvantaged, the low-income folks, are the first people helped in the Cooper-Grandy bill.

Tax reforms which will allow employers to deduct the cost of the most efficient health plans but not the costs of excessive benefits or wasteful spending. In addition, individuals and the self-employed will for the first time enjoy 100 percent deductibility of their health plan premiums.

Mr. Chairman, this is an area—and Mr. Bliley brought this up in his opening remarks—that I think produced the Cooper-Grandy coalition. I too served with Mr. McMillan and Mr. Hastert and others on this committee on the Republican side in crafting H.R. 3080. The reason I didn't think that was a package that we could put before Congress and enjoy bipartisan support on is that it contains a lot of incentives for small employers and for insurance companies and for individuals to acquire insurance, the discipline was not there to control costs and to put the burden of proof on the consumer. That is why I agree with my colleague from Tennessee that a tax cap is the most effective price control that we can impose and get discipline in the health care system right now.

People argue about price controls. It is not a question of whether we impose price controls; it is where we place them. Do we place them at the macro-level and have a global budget and an attempt to stay under it, and premium regulation and an attempt to control

costs with a bureaucracy presiding over the market, or do we put that burden on the consumer, limiting deductibility?

While I am sorry that Mr. Bliley cannot find it in his heart to support the bill right now, I realize that Republicans are going to have a hard time with a bill that stresses both changes in revenue and regulation. These are rubicons that we, on our side of the aisle, normally don't cross. But the fact is, behavior modification of this magnitude involves both, and those people that are on the bill acknowledge that.

That is why I want to come back to what my colleague said about bipartisanship. The one thing that we have to agree on is, we cannot allow major health care reform in this country to pass by what is now called, euphemistically, "a Clinton landslide." Two or three votes maybe with a handful of Republicans, probably not in the House, will not a health care system make.

Republicans stand ready to participate in this debate, to bring the debate back to the center; and we do not claim to have developed the final product here.

Going to Mr. McMillan's comments and criticisms about Medicare, of course that is the dirty little secret we are all dealing with. The Clinton plan proposes to take \$124 billion of Medicare part A, while it expands the program. That is a death knell to every rural hospital in the United States. Recent information I got from the Iowa Hospital Association says that even under the Clinton budget we passed by one vote in 1993, the \$46 billion whack out of part A is basically going to produce a negative operating balance for the average Iowa hospital a negative 5 percent this year.

Imagine what \$124 billion over 5 years will do. There aren't enough grants and loans and incentives to get those doors to open again.

The point is—and I agree totally with my colleague from North Carolina—we have to put Medicare on the table in some kind of reform. Right now we have people over 65 spending the most dollars for care, using the most undisciplined form of care, and that must be part of the equation, too.

Finally, let me say that I hope as we begin this debate today we do argue the substance and not use sniper fire to stress those issues that divide us. There is one area, I think, that will probably be the greatest bone of contention between the forces that support the President's plan and those allied with the Cooper-Grandy coalition, and that is the whole question of the employer mandate, which of course is the litmus test of universal coverage versus the tax cap on deductibility. Both of these are very thorny issues.

Whether or not we agree to global price controls or reduce the size of the alliances and make some of the changes the President indicated he would be willing to do are really, I think, incidental to the final conclusion. We must come to closure on whether or not we will impose an 80 percent premium tax on the employers of America or whether or not we will turn around and impose that burden on the consumers of America by limiting deductibility.

I hope this debate and the debate that will proceed in the Energy and Commerce and the Ways and Means Committees and in other committees of jurisdiction will allow us to solve that problem and



write meaningful health care reform this year that will involve generous Republican and partisan and Democrat support.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you.

[The articles referred to and the prepared statement by Mr. Grandy follow:]

[From the New York Times, February 2, 1994]

## CLINTONS CAMPAIGNING TO SCUTTLE ENDORSEMENT OF RIVAL HEALTH PLAN

(By Gwen Ifill)

Senior administration officials started an intense lobbying campaign today, including a White House meeting between business leaders and Hillary Rodham Clinton, to derail a potentially damaging show of support for a health plan competing with their own.

While President Clinton met today with hospital officials and Governors to promote his plan, his top aides sought to persuade members of the influential Business Roundtable not to back a less comprehensive one sponsored by Representative Jim Cooper, Democrat of Tennessee. The Cooper plan, unlike the President's, does not require employers to pay any of the costs of their employees' health insurance.

The policy committee of the Roundtable is scheduled to vote on the competing health care plans on Wednesday. The Roundtable, established in 1972, consists of chief executives from 200 companies, including A.T. & T., I.B.M. and Pepsico.

The White House charge is being led by Mrs. Clinton, who has been meeting with business leaders for weeks. She has been joined by Thomas F. McLarty 3d, the White House Chief of Staff; Roger C. Altman, the Deputy Treasury Secretary; Robert E. Rubin, the chairman of the National Economic Council, and Alexis Herman, who runs the White House Office of Public Liaison.

Executives of large corporations have objected to the breadth of the Clinton proposal, which they say could slow the economy because of its high cost and could give the Government too big a role in the private health care system. They have also been skeptical of its financing, which would rely on taxes and savings from a predicted reduction in the growth of Medicare.

"We're not asking them to endorse our plan," said a senior administration official who took part in the White House meeting today, which was attended by about a dozen members of the Business Roundtable. "We're asking them to keep their powder dry. That's it."

White House officials are hoping to keep the business leaders neutral in the health care battle so they will not devote resources and political muscle to portraying the Clinton plan as unworkable.

"We're simply saying that it is too early to engage the dialogue of one bill over another bill," a White House official said. "We want the Congressional process, which is just getting started, to have time to lay our course."

As officials worked the phones today, several others, including Harold M. Ickes, the deputy chief of staff; George Stephanopoulos, the senior policy adviser, and Pat Griffin, the Congressional liaison, went to Capitol Hill for a dinner meeting with business leaders arranged by Representative Dan Rostenkowski, the Illinois Democrat who heads the House Ways and Means Committee.

Among those chief executives at the afternoon meeting in the Roosevelt Room of the White House were Edgar S. Woolard of E.I. duPont de Nemours & Company, Robert L. Crandall of American Airlines and Joseph T. Gorman of TRW.

"They're all making tactical decisions," the official said of the executives. "I don't think any of them want the Cooper plan as it is. They're trying to figure out whether it's tactically intelligent to start there."

The White House offensive underscores the delicacy of the moment for President Clinton, who is trying to shore up support among his natural allies and dampen any opposition before it has a chance to solidify. Business groups have proved to be a valuable ally for the President on issues like deficit reduction but they could support an expensive campaign against him if they choose to.

A spokeswoman for the Business Roundtable would not comment on the organization's position today, but in meetings over the last several weeks, several business leaders whose companies already provide generous benefits to their own employees have told administration officials that they are troubled by the Clinton plan's approach. They say it relies too heavily on Government regulation and bureaucracy and might prove too costly for businesses.

In a preliminary tally last month, the policy committee of the Business Roundtable, which has the final say on policy for the group, voted 45 to 14 to support the Cooper bill as "the starting point for health care reform."

#### PROVISIONS OF COOPER PLAN

Mr. Cooper's plan would establish purchasing cooperatives to reduce the cost of insurance coverage but would not require employers to pay for it. Senator John B. Breaux, Democrat of Louisiana, introduced a companion bill in the Senate.

"They've got the big guns," Mr. Cooper said. "I don't even have a pea shooter in this debate. All I've got is a good bill."

In response to such arguments, Mr. Clinton has sought to emphasize that his plan is not a Government solution, that alternatives will cost State governments more and that those who have suggested that a health care crisis does not exist or must be solved incrementally are out of touch with reality.

"You know that the most complex system that could ever be designed is not the one in the administration's bill," Mr. Clinton said to a meeting of the American Hospital Association. "It's the one you're living with right now."

Lisa Caputo, Mrs. Clinton's press secretary, said the meeting today was part of an effort to sway business leaders on elements of the health care plan. But the administration has stepped up its efforts to signal compromise. Governors who met with Mr. Clinton on Monday said he had suggested that he was willing to relax provisions that call for the establishment of regional purchasing alliances.

Those signals irked even some of Mr. Clinton's most loyal supporters. Senator John D. Rockefeller 4th, a West Virginia Democrat who is a member of the Senate Finance Committee, said that Mr. Clinton's comments, as relayed by Governors leaving the meeting, were "not particularly helpful."

But Mr. Clinton is playing on a bigger stage these days, engaging in an escalating war of words with Members of Congress, including Senator Bob Dole, the Republican leader, and Mr. Cooper, over the scope of his health care plan.

"Our approach is not to tell you how to deliver health care, not to build barriers or bureaucracy," Mr. Clinton told the American Hospital Association today. "What we want to do is establish a framework in which people are covered, provide the right incentives, help to remove the barriers to access and get out of the way."

#### 'TINKERING' WITH REFORM

In his public remarks today, Mr. Clinton dismissed many of the disputes that have sprung up around his health care plan as "linguistic battle" and an effort for less courageous politicians to "tinker at the edges" of reform.

But Mr. Clinton is reassessing some of his language as well, emphasizing the need for "guaranteed private insurance" instead of "universal coverage." Last week, Mr. Clinton vowed to veto any health care bill that did not provide universal coverage, and his opponents have suggested that the White House is promoting a complicated and bureaucratic Government remedy.

Mr. Dole, who has aimed many of the harshest broadsides at the administration plan in recent weeks, sounded distinctly more conciliatory today. Speaking to the National Governors Association meeting before Mr. Clinton arrived, he said there was a "growing consensus" among Republicans and Democrats about the need for a restructured health care system.

On Monday, the Governors endorsed a proposal that falls short of the administration's plan. While calling for core benefits to be made available for employees who wish to buy insurance coverage, the Governors could not agree on whether employers should be responsible for paying part of that cost.

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 FEBRUARY 2, 1994

THE MANAGED COMPETITION ACT OF 1993 -- H.R. 3222

TESTIMONY BEFORE THE ENERGY AND COMMERCE,  
 HEALTH AND THE ENVIRONMENT SUBCOMMITTEE

Mr. Chairman and members of the Committee, I appreciate this opportunity to testify on one of the most important policy decisions confronting the United States Congress. Specifically, ensuring affordable, high quality, health care coverage for all Americans.

Today, I am here to provide an overview of health care legislation I am proud to have cosponsored with my colleague from Tennessee, Congressman Jim Cooper. The official title of the legislation is the Managed Competition Act of 1993, however, it is commonly referred to as the Cooper-Grandy bill. It remains the only comprehensive bi-partisan health care reform proposal introduced in the House.

As you are by now aware, the Managed Competition Act is a market-based approach to health care reform. It guarantees universal access to high-quality, affordable health care. Like the President's proposal, the Managed Competition Act builds off of what works in the current system and reforms the chronic problems that have plagued our system for too long. Most importantly, like the President's plan, the Managed Competition Act ensures every American access to a private sector health plan.

I would like to address upfront a criticism that has been leveled against the Cooper-Grandy bill, that we do not provide universal coverage under our proposal. I want to make it clear that we are not opposed to universal coverage. In fact, universal coverage is a goal that Mr. Cooper and I share. I believe that the universal access mechanism in Cooper-Grandy is the best means to achieving universal coverage. These are not mutually exclusive goals. This whole discussion over access versus coverage is really, in my opinion, an issue of semantics. It is more a discussion of time-tables and how do we get to universal coverage. Mr. Cooper and I use a different mechanism than the Administration to achieve universal coverage, but I believe we share the same underlying goal. I am here to offer my aid in achieving our shared goal of ensuring that all Americans are covered under a system of health care that provides the quality of care Americans want and deserve.

Our bill uses a series of strong tax incentives that will encourage providers and insurers to form accountable health partnerships (AHPs) which, for the first time, will be publicly



accountable. Accountable not only for the cost of the care they provide but also for the quality of that care. This will enable consumers to purchase health care coverage in a much more cost conscious manner than they do today. It will also provide them with the information necessary to truly determine which of the plans available to them provides the highest quality of care.

To help facilitate individuals' and small businesses' access to these new AHPs and ensure affordability, regional purchasing cooperatives will be developed to give individuals and small businesses the benefits of greater buying power currently enjoyed by larger employers. A national Health Care Standards Commission will establish a uniform set of effective health benefits which AHPs will be required to offer in order to receive tax-favored status. In addition, AHPs will be required to comply with a series of insurance reforms and disclose information on medical outcomes, cost-effectiveness and consumer satisfaction.

Specific components of the Cooper-Grandy bill include:

- 1) Insurance reforms that will encourage insurers and providers to combine and form AHPs. AHPs will not be allowed to exclude coverage of pre-existing conditions and will not be allowed to charge higher rates based on an individual's medical history;
- 2) Access provisions which will ensure individuals' and small businesses' affordable coverage by joining Health Plan Purchasing Cooperatives (HPPCs). HPPCs will offer group rates with lower administrative costs. Once a year individuals will be able to choose from a menu of AHPs in the area much like the current Federal Employees Health Benefits Program;
- 3) Provisions to change the incentives in the system from "more money for more services" to a system: in which health plans are pre-paid so they will have incentives to promote preventive care; which eliminates unnecessary tests and ineffective treatments; and which reduces administrative costs. Because AHPs will be required to provide information on health outcomes and beneficiary satisfaction, they will be driven to improve quality;
- 4) A federal low-income assistance program will pay health plan premiums for all people below 100% of the poverty level. Individuals between 100% and 200% of the poverty level will receive sliding-scale subsidies toward the purchase of a health plan;
- 5) Tax reforms which will allow employers to deduct the cost of the most efficient health plans, but not the cost of excessive benefits or wasteful spending. In

addition, individuals and the self-employed will for the first time enjoy 100% deductibility of their health plan premiums;

6) A series of provisions and additional resources to assist underserved areas in recruiting and retaining providers, the development of provider networks, integration of public health clinics and coordination with urban medical centers; and

7) Savings mechanisms such as enhanced competition among health plans, anti-trust reforms, significant malpractice reforms, administrative simplification and electronic claims processing.

Mr. Chairman, this committee has heard various approaches to expanding access and ensuring affordable health care coverage for all Americans. These range from proposals that would eliminate the current system and replace it with a Canadian-style system, to proposals that would eliminate the current tax deduction provided businesses for their health care expenses and replace it with an individual tax credit. Our proposal clearly comes in well to the right of the single-payer approach and left of the medical IRA approach. On a spectrum with these two approaches as the respective left and right ends, our proposal comes in on the fifty yard line, building upon the very best aspects of our current system and providing the flexibility necessary to address the deficiencies within that system.

As important as the specific policies included in any legislative framework, are the politics involved in building a coalition to pass health care reform. In that regard I submit that the Cooper-Grandy legislation provides the foundation for bipartisan reform because it represents a true bipartisan approach to reform. Unlike the single-payer approach, the Administration's proposal, the House GOP proposal, and the medical IRA approach, the Cooper-Grandy bill remains the only bipartisan approach.

We do not claim to have developed the final product of this debate; only the legislative process itself can accomplish that. We do however have the only proposal that has shown a good faith effort to put aside partisan positioning and work together across the aisle and on both sides of the hill, and as such, I believe the Cooper-Grandy bill represents the best starting point for the upcoming debate.

Thank you once again for holding these hearings and providing me with this opportunity. I would be happy to answer any questions at this time.

Robert J. Samuelson

## The Dishonest (and Nasty) Health Debate

A year ago, I held out the hope that we might have an honest health care debate. Perhaps inevitably, it hasn't happened. On the one hand, President Clinton's plan is hugely dishonest. It offers almost everything to everybody. It would mandate universal health insurance, control costs, expand Medicare and provide new benefits for early retirees—all without imposing major new taxes, threatening the quality of care, reducing patients' choice of doctors or requiring federal price controls. The only thing it doesn't promise is immortality.

On the other hand, Clinton's critics now declare that the health care "crisis" doesn't exist. This refusal to face reality provides good care for most people. But the argument is dishonest because it wrongly implies there are no serious problems: high costs, spotty insurance coverage and genuine public anxieties about both. Everything won't get better spontaneously.

Both Clinton and his critics skirt the real problem: Most Americans expect far more from the medical system than it can deliver. In general, we think people should have good care when they need it. Costs should be no bar; insurance should pay. The issue is a moral one. But naturally, we don't want soaring insurance costs to raise our taxes or depress our salaries. All these are worthy goals—but only if they don't lead to health "needs." If we have all the care we (or our doctors) say we need, costs will skyrocket. So, controlling costs means curbing some treatments or excluding some

controls; and (4) the "insurance cycle" that creates wild swings in premium charges.

Clinton's spending will speed up in a few years. Underlying cost pressures remain expensive and growing. Aging demographics, an aging population and high public expectations for care will drive up costs in spending have proven temporary. In 1984, the Reagan administration claimed that health inflation had been "broken." And indeed, health spending stabilized at 10 percent of the economy's output (gross domestic product) for four years. But then it jumped again; by 1991 it was 13 percent of GDP.

Whatever happens, the spending slowdown has been achieved at the expense of other goals. The number of uninsured has grown. Among the insured, per capita costs are straining. A Peat Marwick survey of 1,000 companies found, for example, that 58 percent of their workers are now enrolled in "managed care" arrangements, double the 1988 level. Although managed care has advantages for family doctors (an HMO), lots of choices isn't one of them. The choice of a doctor is a matter of life and death.

No health plan, however, will need to be judged against the alternatives. Clinton is doing nothing. In its present form, Clinton's plan is worse than it solves. Yes, it could provide universal coverage. But it could needlessly disrupt doctor-patient relations, intensify spending pressures and—because it is so complex and contradictory—spawn massive unintended consequences.

The alternative to Clinton's plan, though, isn't simply to keep government out of health care, as

many conservatives imply. In truth, the biggest player in health care is already the government. It pays two-fifths of all health bills, mainly through Medicare and Medicaid. It heavily subsidizes private insurance, because employer-paid insurance is not taxed as individual income. (That is, your employer pays \$4,000 for insurance for you, but you don't pay taxes on the \$4,000.) The real issue is whether government policies can be improved.

It won't be possible unless we decide what we really want. To control costs? To cover the uninsured? To preserve quality of care? Every problem has remedies. To curb costs, we might impose strict spending controls or end tax subsidies for insurance. But the solution to one problem may aggravate others. Spending controls might undermine the quality of care. Ending tax subsidies would mean that employers would buy less insurance; paying more of them bills, arguably, would make people more cost-conscious. But it might also mean they would receive less care.

Hardly anyone wants to raise these discomfiting choices. There seems to be a presumption that Americans are too dim-witted to grasp the dilemma. The White House started the debate dishonestly, as critics have responded in kind. What we have now is a titanic struggle to win the battle of public opinion. Each side contends that the other (government or private medicine) can't be trusted with the health care system. It's Public Incompetence vs. Private Greed. The media war is engaging. But as a debate, it sheds more darkness than light.



## White House Lobbies Strongly to Block Business Support of Rival Health Plan

By HILARY STOUT  
And RICK WARTZMAN  
Staff Reporters of THE WALL STREET JOURNAL

WASHINGTON — The White House lobbied aggressively to stave off an embarrassing vote by an influential business group in favor of a rival health-care bill.

The Business Roundtable, a group of chief executive officers of some of the nation's largest corporations, is scheduled to vote this afternoon on a recommendation by its health-care task force to support legislation authored by Rep. Jim Cooper (D., Tenn.) and Sen. John Breaux (D., La.).

The prospect of the business group backing the Cooper bill led the White House to invite a group of top executives to meet yesterday afternoon with Hillary Rodham Clinton and senior administration officials. President Clinton himself dropped by for a few minutes, according to participants, underscoring the urgency of the Business Roundtable vote.

Among those at the meeting were the chief executives of TRW Inc., **Procter & Gamble Co.**, **Boeing Co.**, **Aluminum Co. of America**, **DuPont Co.** and **UAL Corp.**'s United Airlines.

Administration officials, including economic adviser Robert Rubin, Deputy Treasury Secretary Roger Altman and senior White House health-care aide Ira Magaziner, told the group that it would be unwise to back a particular health-care bill at this stage.

"We told them to look at all of the options on the table," said Alexis Herman, who heads the White House's office of public liaison. "Why foreclose your options this early in the process? We think that's a message business understands."

### Willing to Compromise

The administration officials stressed that they understand the business community's concerns about the Clinton health-care plan. But they said the president has shown he's willing to compromise on such issues as caps on health-insurance premiums and the shape of proposed regional insurance-buying pools.

Beyond that, the administration officials questioned why the CEOs would want to endorse the Cooper bill when it wouldn't guarantee health coverage for everyone. They noted that big companies already provide medical insurance for their workers. President Clinton has made "universal coverage" the one point on which he won't yield, even threatening to veto any legislation that doesn't meet that standard.

Ms. Herman denied that yesterday's meeting was a last-minute scramble, characterizing it instead as part of a continuing effort by the administration to reach out to business leaders. But the White House clearly is worried about the bipartisan

support the Cooper bill enjoys.

At the White House's request, Reps. Dan Rostenkowski (D., Ill.) and John Dingell (D., Mich.) have been contacting companies to make the administration's case. Rep. Rostenkowski called a group of top executives to a meeting on Capitol Hill last night. In addition, Messrs. Rubin, Altman, Magaziner and White House Chief of Staff Thomas McLarty have been working the phones. Among those who have been contacted by the White House are **Eastman Kodak Co.**, **Ford Motor Co.** and **Xerox Corp.**

If the White House succeeds in quashing a roundtable vote in favor of the Cooper bill, it will be a considerable victory. The pro-Cooper resolution already was approved by the roundtable's policy committee in a lopsided vote earlier this month. But the White House asked the business group to delay announcing the vote until after the president's State of the Union address last week. The roundtable agreed to reconsider the vote at its policy committee's annual meeting today.

### Clinton Attacks Insurers

While the administration lobbied roundtable members yesterday, President Clinton stepped up his attack on the nation's health-insurance industry. In two separate speeches, he asserted that insurers are wasteful, discriminatory and an impediment to a fully functioning health-care system.

"Insurance companies have set up a system which enables them to slam the door on people who aren't healthy enough to get covered," Mr. Clinton charged during a speech to the American Hospital Association. Later, he told the National Governors Association: "We do have a system, unlike any other in the advanced countries in the world, in which insurance companies decide who's covered and who isn't, what the cost of insurance is, and what's covered in specific policies."

Democrats on Capitol Hill also scorned the insurers. At a Senate Finance Committee hearing, the health-insurance lobby heard angry words about its multimillion-dollar advertising campaign designed to undercut the Clinton health plan. "You're scaring people," said Sen. Jay Rockefeller (D., W.Va.) in a sharp exchange with former Rep. Willis Gradison, an Ohio Republican who resigned from Congress last year to head the Health Insurance Association of America. Mr. Gradison noted that his group supports many insurance reforms in the Clinton administration's bill.

Sen. Rockefeller also suggested that the president's professed willingness to compromise on such issues as the premium caps wasn't "particularly useful." In response, Mr. Clinton later said, "I would caution Sen. Rockefeller to not think that I have left his position. If we change positions, he and I, we're going to try and do it together."

Jeffrey H. Bernstein and Michael K. Pressly contributed to this article.

Mr. WAXMAN. I will start the questions. I want to commend both of you for the work you have put into developing your plan, the thoughtfulness with which you have approached this subject.

We do have similarities in all the plans. We would reform insurance practices; there are slight variations, but President Clinton would do that, your bill would do it, to some extent the Republican bill would do it as well, so people who have insurance won't have it taken away, preexisting conditions won't preclude them from coverage. That is an important change.

A lot has been said about the fact that your legislation does not provide universal coverage. I think that is an important point because I wouldn't want it to be a hollow promise to the 39 million people without insurance in this country that we are going to pass insurance reform and then large numbers of them, as many as 39 million, still may be without coverage.

But I want to focus on something else, and that is the theory behind this legislation because you do have an intellectual theory that we are going to have markets, competition, forces that competition brings about to hold down health care costs; is that an accurate statement? You want to see market forces work?

Mr. COOPER. Not pure markets, not laissez faire, but managed competition.

Mr. WAXMAN. To a great extent, your bill is pure managed competition with attachment to the Jackson Hole Group that developed the idea of injecting market forces. The idea of market forces is that consumers ought to be better shoppers. You say it is empowering them to be better shoppers. Your tax cap is to make them better shoppers by making health care more expensive for them, so that they will shop around for something that is going to be reasonably priced; and the theory then would be that plans would be more efficient to try to attract the consumers.

Isn't that the idea of the tax cap and the change in tax deductibility?

Mr. COOPER. If I could respond in some detail, because this is a very detailed issue.

Mr. WAXMAN. The problem is that I have only a few minutes.

Mr. COOPER. I would be happy to grant you additional time.

There are two major tax break programs working today in America. Combined, they are the Federal Government's third largest health program at \$75 billion a year.

Mr. WAXMAN. There is a tax break that employers can take now, but self-employed can't. You would give the self-employed ability to deduct it. Employers—the employers are not taxed for the benefits, for the health insurance. You don't change that?

Mr. COOPER. We don't change that.

Mr. WAXMAN. You are saying what employers can deduct now is the price for the lowest-priced health insurance package; is that correct?

Mr. COOPER. The last unlimited corporate fringe benefit today in America not tax limited is health insurance. We would not eliminate that. We would trim it to the price of the lowest-cost, basic—

Mr. WAXMAN. So if employers can deduct only the price of the lowest-cost health insurance policy, how does that make the em-

ployee more cost conscious? Is it because the employer will say to the employee, this is all I am going to provide you, now you come up with the rest of the money to buy your policy if you want more than the lowest price?

Mr. COOPER. I think you are looking at it at the wrong end.

Most citizens are unable to deduct any health insurance cost today. We would grant them new deductibility for the first time in their lives for whatever portion of the basic benefits package that they are buying. That will involve the individual citizen in noticing what is a fully or partly deductible plan. Even the partly deductible plans will still be like 80 percent—

Mr. WAXMAN. Would it be likely that employers faced with higher taxes on them are going to say, they are going to provide only that insurance which is tax deductible and let the employee pick up the rest? If they go higher than that, they will get a tax deduction, which means government will help them pay for part of their insurance.

But rather than ask you that question, in effect, when all is said and done, if your bill becomes law, won't that mean that most Americans will find that they are going to pay more out of their pockets for the health insurance coverage they are now getting free from their employers who are taking it as full tax deduction?

Mr. COOPER. I disagree and would like an ample opportunity to explain our views.

Mr. WAXMAN. Without objection, I am going to proceed for another 5 minutes to give you the opportunity.

Mr. COOPER. We do not affect in any way the current tax exclusion which is, when the boss buys health coverage for the employee, that is not counted as income to the employee. That is a policy that we leave in place. If we were to tamper with that, that would be a middle-class tax increase. We don't touch it.

Mr. WAXMAN. My question to you is, if an employer can't deduct the full cost of the insurance except for the lowest-priced plan for each employee, isn't that an incentive for employers to say that is all we are going to provide? They are going to pay more taxes if they provide the present level of benefits that exceed the lowest-priced plan.

Mr. COOPER. If you look at other corporate fringe benefits, including executive compensation, life insurance, child care, parking, all are tax limited. That does not prevent corporations from doing more than the minimum required in all these areas. It will encourage people to shop for value.

If the more expensive health plan is worth it, people will buy it. If it is not worth it, they probably won't, bearing in mind that sometimes—increasingly often—the lower-priced plans give you the best value.

Mr. WAXMAN. They may well give you the best bargain, but for those people that are below 100 percent of the State poverty level, you give a full premium subsidy. For those on a sliding scale, until they get up to 200 percent of the State poverty level, they get less than the full subsidy, but it is based on the lowest-priced plan. So those people are only going to get a choice of the lowest-priced plan.



For working people, if they are over 200 percent of poverty—for a family of three, this is \$23,780, less than \$2,000 per month—so if an annual premium for that family will be \$4,000, which is below the estimate of \$4,400 for the administration standard plan, provided by the Hewlett Associates, that family will now have to come up with what is, in effect, 70 percent of their income for health insurance. If they can afford that, they are not about to buy a higher-priced plan—probably a lowest-priced HMO.

If you are going to make consumers comfortable, if that is your goal, what in effect the American people will wake up and find is that they are being told to pay more if they want more than the lowest-priced HMO; and I think the reaction of the American people is going to be one of outrage if they find that placed on them.

Now, we can tell them if we want to be honest, we want you to be better shoppers, more careful in scrutinizing the cost of health care; that is an important message. But that is not what they think they are getting, because the Clinton administration doesn't plan to do that.

Mr. GRANDY. Could I weigh in on this?

Mr. WAXMAN. Well, you two decide.

Mr. GRANDY. You keep talking about the lowest-priced accountable health plan. Don't forget that this bill, like the Clinton bill, does authorize a standard benefit plan. Will it be a so-called Cadillac plan that is conceived in the Clinton bill? Probably not. Will it be some kind of low-ball discount package? Definitely not. To assume that all employers will necessarily go to get the deepest discount is to presume that benefits are not a competitive item in the bargaining place. We know they are.

The alternative is to allow the government to set the standards—

Mr. WAXMAN. Whatever the choice is, it is going to be the lowest-priced HMO. A lot of people don't want to be in the lowest-priced HMO. First of all, the poor people are the only ones going to be in there to start with. Then they will have a choice. Do they want to be in the poor people's HMO or do they want to buy themselves out of it? I submit to both of you that your tax cap proposal, as worthy as it may be from an intellectual point of view if you accept the theory of market competition, is not going to pass the Congress, because I don't think Members of Congress will vote for a tax increase on middle-class Americans.

Mr. Bliley pretty much said he is not willing to go along with that either.

I guess if your proposal comes up and there is no tax incentive to be more scrutinizing as a shopper, or as you would put it, empowered to be a shopper because you now have a financial burden on you, your proposal, then, without that tax cap, is pretty much the same thing as the Republican proposal. Is that how we are going to get bipartisan support, no guaranteed health insurance for the uninsured and nothing by way of market forces?

Mr. COOPER. Mr. Chairman, the 50 Governors on a bipartisan basis endorsed a tax cap this week.

Mr. WAXMAN. God bless them. They don't get a vote in this institution. Do you think you can pass a tax cap in the Congress? We will have to see whether that is the case, but that will be the issue.

Mr. McMILLAN. Will the gentleman yield?

I think the President's plan itself has a tax cap in it and also taxes benefits to the employees, so the assertion that this plan is unique in that respect is not the case.

Mr. WAXMAN. The gentleman has to look at the President's plan more carefully. He would phase it over a longer period of time. The President's plan is premised on one basic idea that nobody should be worse off than they are at the present time. If you don't have insurance, you will have coverage. If you have insurance, you are not going to be forced to pay a lot more money for it and we are going to try to standardize it so people really get choices, not force them into the lowest-priced HMO because that is all they can afford.

I submit this is the consequence of this.

Mr. Greenwood, you are next on the Republican side for questions.

Mr. GREENWOOD. Thank you, Mr. Chairman.

It is the tax policy of the Cooper-Grandy proposal that has been the Rubicon between me and sponsorship of the bill. I understand you have two purposes: One is to raise the money to provide the funding for the subsidy for those individuals under 200 percent of poverty; the other is to change behavior in the marketplace.

I would like to give you ample opportunity to explain to us what your intentions are, what the intellectual theory is, and also let us know if there is some room to move on this.

Mr. GRANDY. If I can begin on this, I want to go back to something Dr. Koop said when he introduced the First Lady to Congress this fall when we first began our informal discussions of this. This is a point that is worth stressing every day.

He said that one of the problems in this country is not just that too many people have too little insurance, but too many people have too much and that is the purpose behind the tax cap. It is not the low-cost, discount, accountable health plan that we are trying to force everybody into. It is the high-priced, Cadillac plan, subsidized out to everything from in vitro fertilization to veterinary benefits that we are trying to reduce the subsidy for.

What we are essentially trying to do through the tax cap is redistribute some of the benefits and the opportunities to the people that have nothing or too little.

Is it flexible? As we said, I think, in both of our arguments, this is the beginning of a debate. This is our opening gambit, to hold the center of this debate and maintain bipartisanship. I can't recall, but it seems to me that when CBO costed out our program, we were talking about a basic benefit of \$2,100 per individual, that if you cost it out, it is more expensive than what the Clinton plan originally envisioned.

If that is to be the deductibility, is that written in stone? Not in my view.

Mr. GREENWOOD. Why cap the deductibility at the level of the lowest-priced policy as opposed to perhaps the average-priced policy, which might make middle-income families feel more comfortable?

Mr. COOPER. The key question is whether you want bureaucratic price controls or market controls. Our approach is tougher than the

approach you suggest. If you want less cost-containment, endorse the average, but realize the consequences.

Our approach is to help every American afford Chevrolet benefits before we subsidize anyone's Cadillac benefits. If you want Cadillac benefits, fine. You can still get to deduct most of them, but the leather seats and the sun roof you pay for with after-tax dollars.

There is a real fairness question here, because people in America who make over \$100,000 receive 30 times greater benefits from today's tax expenditure system than folks who make lower income, under \$10,000. This system has been so ignored for so long that we have forgotten the unfairness and waste that is in the system.

Lee Iacocca's successor today at Chrysler Corporation could fully deduct a policy to send him to Switzerland if he was afraid he had the hiccups, no questions asked. Meanwhile, a poor family working for a small business, struggling to get by, their boss can't afford to buy them coverage, cannot deduct one red cent of their health coverage. To the extent they are a taxpayer, they are subsidizing the Chrysler decision to buy that fancy policy.

That doesn't make sense, but we have lived with it for so long we have forgotten to explain.

We have to bring fairness and equity into this area. These are classic democratic principles, classic bipartisan principles. These are things that we can all agree on. The only tax increase here is for corporations, and most corporations understand the need for it. The only individual tax change is a new tax break worth \$54 billion over the next 5 years. That is a good deal.

In negotiations a 1½ years ago, we came this close, even with the AFL-CIO, to cut a deal in this area; plus when you are calm about it and you understand the tax laws, you understand the need for it. That is why it has such wide support even though it is still a political hot potato.

Mr. GREENWOOD. You referred to some cities where managed competition has been in effect. What do we know about the cost-containment results in those areas?

Mr. COOPER. Donna Miller from Memphis will testify on the next panel. I encourage you to inquire in your own area.

It is widespread, the market miracles that can occur when you allow market forces to really work, strong purchasers taking on the providers and demanding and getting a better deal.

Mr. GRANDY. From my own point of view, the community I live in has embarked on a managed competition model called Care Changes. Doctors, consumers, hospitals, all providers and all consumers are finding it is something that we can live with and something that they prefer to the system they used to have.

That is the bottom line, not necessarily how much money is saved out of the system.

Mr. WAXMAN. Mr. Wyden.

Mr. WYDEN. I thank our colleagues for an excellent presentation. I am not a cosponsor of any of the bills, but planning to work closely with you both.

My concern about the Cadillacs and Chevrolets is that you all take away the right to the Cadillac, which is fine, but you don't guarantee the right to a Chevrolet. I don't see spelled out in the



bill the right of access to that basic Chevrolet or even Yugo benefit package.

I come from a State where we made some tough calls, so we are guaranteeing everybody in the State of Oregon, because we swallowed hard, the right to—characterize it by your terms—the right to a Chevrolet. How would you respond to that?

Mr. COOPER. Perhaps my friend can support the sort of harsh government-imposed rationing that Oregon is engaged in. I prefer market forces. If you have to choose between services that you want or don't want, let the individual patient decide, based on real costs, so they are informed and empowered.

Our tax change is good news for every American. We are not as versed on this committee about these technical tax details, but I would be delighted to go into detail with the gentleman, because most prior proposals in this area did not deal with the deduction. They dealt with the exclusion. This is a different thing that we are talking about.

It is important, working with Joint Tax and CBO and others, to understand the real economic implications here. The so-called tax cap is one of the linchpins of managed competition. Either you have that sort of price control or you are inviting the bureaucrats to run the system; and I don't want that.

Mr. WYDEN. Oregon had public meetings, 40 meetings across the State. The people chose the benefits package. They are now guaranteed the right to a Chevrolet. Under your plan, they are not guaranteed, as far as I can tell, anything.

Because time is brief, I want to go into the matter of the employer mandates. As I read it, you are out of step with the American people on the employer mandates. Poll after poll has shown that the majority of the American people now believe that this should be some version of an employer contribution on health. We can debate what it is, whether it ought to be 80/20 or something else, but my concern is, why can't we have some version of shared responsibility where the employer does a portion, the employee does a portion? I am very open to work with you on what that ought to be.

We can talk, when phasing it in, about multiple standardized packages. We did that on the medigap law and it has worked well. I would be for a circuit breaker which would indicate that if employers had problems with an employer mandate, the government would help them. What is wrong with some version of shared responsibility when the majority of Americans are now saying that is what they want?

Mr. COOPER. I am all for shared responsibility. Most employers do that already on a voluntary basis. Government coercion should never be a first resort. It should be a last resort. When those pollsters ask the question and tell folks that even the White House has said that 600,000 Americans could lose their jobs as a result of an employer mandate, which is a tax on jobs, support for the employer mandate goes way, way down.

We need to be reforming health care and creating new job opportunities in this country, not reforming and costing 600,000 jobs.

Mr. WYDEN. On the employer mandate, my concern is, for people who want a private sector system, which you want and I want, un-

less we have some version of shared responsibility what will happen in this country is we will see a federalized system like the Canadian system; Americans will be concerned that their doctor is running around with a white coat that says "Commissar" on it, and I think we have to have some version of shared responsibility.

I have time for one last question. Are you open to reconsidering your position with respect to abortion and the right of free choice? We have got millions of women in this country who are concerned that your proposal retreats from rights they have right now under the law. Would you all reconsider that in the name of again trying to work out a bipartisan compromise?

Mr. COOPER. The bill we have is silent on the abortion question as is the Clinton bill. Groups like NARAL have approved of our bill for the last 2 years, and suddenly last week they have discovered that our silence is not acceptable but Clinton's silence is.

We have strong supporters on our bill who are pro-choice and pro-life because we are silent on this issue.

Mr. GRANDY. Mr. Cooper is pro-choice, I am pro-life.

One of the reasons I find this bill a meaningful compromise is because it does acknowledge that *Roe v. Wade* is the law of the land; you have a right to an abortion, but not necessarily the subsidy.

I think the reason we stay silent on that is because that is still a very contentious issue before Congress. We haven't decided whether or not that is something that should be extended fully through Medicaid. That is something that States are wrestling with right now.

I would hate to see a debate over national health care or health care reform degenerate into another fire-fight over abortion. I would encourage any plan to remain neutral on abortion, so that we do not re-ignite a battle that I don't think any of us can win, no matter what side of the fight we are on.

Mr. WYDEN. The Clinton package does cover reproductive health services. That is something in the basic benefit that is not in your package. I do think that is a retreat, but I intend to work closely with you both.

Mr. GRANDY. We do not specify a basic benefit package in the bill. So if abortion is not in there, neither is lower back pain.

Mr. WAXMAN. Mr. Klug.

Mr. KLUG. There are a number of supporters of this bill who are pro-choice and who think that in whatever way we reconstruct the system that you cannot deny reproductive rights to women who already have it under private insurance. So a number of us are going to work on that area.

Let me go back to some of the questions the chairman raised. It is your intention in the bill, if I am correct, to establish a basic benefit package. If you establish a basic benefit package and people begin to look for the lowest-cost health care system in terms of the lowest-cost benefit package, if the benefits are all the same, nobody is going to be discriminated against; is that correct?

Mr. COOPER. Exactly. In defining the basic benefits package, we prefer to keep politicians out of the process because we are not health care experts. We would like that package to be defined "all medically necessary and appropriate services," have real health

care experts put it together, and we vote on it, yes or no, without amendment. That will be a great package. That will not be a denial of service to anyone. It will not be a Cadillac, but it will be a good package.

We think that all the plans on the menu will be of that quality. They will differ in price, clinic location will differ, doctor membership will differ, medical delivery system will differ, but the public will be empowered with price and quality and consumer satisfaction information so they can choose what the best service is.

Mr. KLUG. If my company decides to move from Plan A to Plan B because it is a cheaper price, because of the changes in the tax laws, it will essentially still be the same set of benefits. I may like it better because of its quality or a doctor I worked with over the years, and the additional cost may be worth it to me.

Mr. GRANDY. I think the difference will probably be in the way those basic benefits will be delivered. But I don't think an employer, given the fact that 85 percent are trying to provide benefits voluntarily, is necessarily going to go to a rigid staff HMO model just to cut it down in price if he has been delivering something more generous up to this point. I don't see this enormous disinvestment in the workplace.

I will say that one of the reasons that we did not—and we specifically did not in our bill—legislate the benefit package is because we know, based on our attempts to do that through Medicaid and Medicare, what a political process that becomes. Having sat on the Health Subcommittee for 2 years, I can tell you every single provider, alternative or otherwise, has come before the Health Subcommittee and said, we deserve to be in the basic benefit package.

The only benefit we have conclusively ruled out is life after death at this point. But that gives you an idea of what we are talking about.

At some point, somebody has to make a decision as to what a basic benefit is. We feel that should be done by a base closing model as opposed to a political model that will probably allow special interest groups, rightly or wrongly, to get in.

Although I think the price change will be in delivery, I don't think you will see an enormous disinvestment in delivery systems that are currently being provided.

Mr. KLUG. I agree.

Let me talk about another area that I think your bill is a vast improvement over the President's, and it is the idea of self-insured plans. Under the President's plan, every business of 5,000 employees or more has to belong to the purchasing cooperative, and for the State of Wisconsin, that essentially means everybody except three major businesses.

We have in the Madison area three large companies—Nelson Industries which makes industrial mufflers; Stohlton Trailers, which makes tractor-trailers; and Ray-O-Vac, which makes batteries. All three are self-insured, all have employees between 1,500 and 2,500, and today their basic health care costs are essentially the equivalent of 3.5 percent of payroll.

Under the President's plan, they will rise to nearly 8 percent, which essentially means for some of those companies anywhere from \$1 million to \$2 million more next year for health care bene-



fits. I fear what that means is a severe loss of jobs for all three companies and others.

Why the difference between the President's over self-insured plans?

Mr. COOPER. You are pointing out a very important part of the President's bill. The limitation in the President's bill that no company would ever have to pay more than 7.9 percent of payroll is a massive redistribution of income in corporate America. It is a bailout for our largest and most inefficient companies, and it is a penalty for some of our most efficient companies.

For companies like yours, who provide in some cases full family coverage, 100 percent paid for less than 7.9 percent coverage, all of a sudden they will be penalized by having their obligations raised; but other companies that have bargained differently and have whopping health care costs are suddenly going to be given a terrific windfall, hundreds of millions of dollars at taxpayer and more efficient company expense.

This is a key issue and one of the reasons that we rely on smaller and less regulatory alliances. Our number is about 100 employees or less, and we are thinking for about half a work force in an area to be enrolled in our health alliances, half outside but working for larger companies.

Mr. GRANDY. Iowa is similar to Wisconsin in that I don't think, with the exception of one major employer, there is a business that would basically be able to go into a corporate alliance. I feel most will go into regional alliances because it would be a better subsidy for them.

On self-insurance, that has been an area under ERISA that companies have used to get health costs under control. It has been successful, but it has also been abused. One of the reasons we do have a mandatory purchasing cooperative threshold of 100 businesses is we don't want some company of 25 to self-insure and basically create something that is actuarially unsound. That number was given to us as a threshold, below which you probably would run into some problems, but above which self-insurance is viable.

What we are trying to do is not take away tools that have already worked in the marketplace for smaller employers; and in a State like Iowa and probably to a lesser degree in Wisconsin, 100 employees is a big workplace.

Mr. KLUG. Thank you.

Mr. WAXMAN. Thank you, Mr. Klug.

Mr. Kreidler.

Mr. KREIDLER. Thank you, Mr. Chairman.

Mr. Cooper, in your opening statement you made reference to several States that are, so to speak, field-testing health care reform presently. You mentioned Oregon with a somewhat less than complimentary tone to your voice.

How do you perceive the Tennessee plan as it is presently constructed and operating?

Mr. COOPER. Many States are facing funding crises due to their Medicaid burdens. Tennessee is not alone. Many States are scrambling with different solutions, and Tennessee asked for Federal flexibility in order to avoid a giant tax increase on our people.

Any State is going to have implementation problems, no matter how well thought out or carefully drafted the plan is. If I were in Oregon, I would hate to be a poor person with disease number 584 on the list or whatever the cutoff is.

I respect the different States working their way through these problems. I wish that we had acted at the Federal level faster. I wish that we had not burdened the States with these obligations.

Mr. KREIDLER. Does that mean you would endorse, then, Tennessee's approach to health care reform?

Mr. COOPER. That is a State-level reform. I am a Federal official. I wish we had acted in Congress earlier so that States wouldn't have been put through the fiscal crises that they have put through.

Different States will work through different problems in different ways.

Mr. KREIDLER. The reason for getting into that is because a number of States have come forward with proposals. My State is one of those that you listed in your opening statement, the State of Washington. You also state that you have some concerns about States doing their own thing within certain constraints. The State of Washington has enacted managed competition with an employer mandate. I was part of the commission that held hearings all over the State and responded not to government dictates, but to what the people called out for, to address the challenges of universal coverage and to control costs.

One of the problems we have right now is the ERISA preemption for self-insured companies. That needs to be waived for the State of Washington so that they might be able to enact their health care program. Can I count on your support for the State of Washington to have that ERISA waiver?

Mr. COOPER. I am not a Washington health care expert. I know that you are. I look forward to learning the details about the plan.

Do they have a pending waiver request?

Mr. KREIDLER. I introduced legislation last year for that purpose, so it is before the Congress in that respect.

Mr. COOPER. I look forward to working with the gentleman to better understand the Washington situation.

Mr. GRANDY. If we could get you on the Cooper-Grandy bill, I think I could persuade Mr. Cooper to help you with that waiver.

Mr. KREIDLER. I would consider that an endorsement of an employer mandate.

Following in the same vein here, that we all agree on the need for guaranteed-issue, coverage of preexisting conditions, community-rating and other insurance market reforms, but we also know that these reforms would raise health insurance costs for many employers with young and healthy employees, and we could expect many employers to drop their health plans if they are not required to keep contributing, especially if they lose part of the current tax deduction. Why do you think your plan will increase the number of people with coverage instead of decreasing that number?

Mr. COOPER. I don't want any employer to drop coverage that they are currently providing. I don't think that any sensible employer would even think of doing so. The labor market is increasingly tight. Companies are inviting an employee to leave if they in any way curtail benefits because we are creating portable health

coverage for the first time. We are eliminating job-lock. We are telling every employee, you don't have to stay with the old boss, you can go to a new and better job, you are free because we finally made health insurance portable the way we should have done years ago. So if an employer shortchanges employees, he will be in serious trouble by losing his best people.

Mr. KREIDLER. We are still looking at a significant number of people who are not going to have health insurance, and we are obviously looking at continued cost-shifting. That results in inability to control the cost of health care in this country, which is part of the spiral that we find ourselves in right now.

Mr. GRANDY. Are you talking about, supposedly, the young healthy individual that is opting out of insurance now because they would rather have the cash to spend on something else? That is the part of the population that under Cooper-Grandy would not be the first to line up for coverage.

Mr. KREIDLER. It would be an employer with a work force with those characteristics.

Mr. GRANDY. Let me take my daughter as an example. She is 22 years old, she is an actress in New York of all things—

Mr. WAXMAN. It would be worse. She could be in Hollywood.

Mr. GRANDY. Give her time, Mr. Chairman. She has got to pay her dues first.

The point is this. She is one of those healthy young people who has decided all she really needs right now is catastrophic coverage. I am not so sure that is a terrible choice for a young person to make right now, and I am not sure that if we had the empowerment in place for young people, whether they were self-employed as she is, because she is an entertainer, or whether they were working for a tool and die company that was not able to provide a benefit at this point, giving them the option to find a policy they could afford would not bring them into the marketplace. The point is, let's conduct the experiment and find out.

A lot of these people are precluded from buying policies, one, because it is too expensive or, two, because they say it is not worth the investment right now. As I understand the Clinton plan, those people would not be assessed unless they showed up with some kind of traumatic injury or illness, and at that point when they actually enter care, they are assessed on a retroactive basis for not being in the program.

I am not sure that is cost-containment, either.

Mr. KREIDLER. If they are employed, there would have been an employment contribution in the plan, which is not true in the case of somebody who opts not to have health insurance and then goes in and accesses the system and winds up cost-shifting to everybody else and billing it into our premiums.

Mr. WAXMAN. Mr. McMillan.

Mr. McMILLAN. Thank you, Mr. Chairman.

Having come from business and having set up health insurance plans for a company of 7,000 people some 20 years ago—it was more full than the President's plan, more full than is contemplated in most plans—I am convinced that most companies don't set up insurance programs for their employees because of tax deductibility. Compensation is deductible; every expense they have is deduct-



ible. Most are trying to cut costs. If anything, they have insurance plans because it makes for a good work situation, part of our work tradition.

There are some businesses that can't afford it, and that is one of the things that we are trying to address here. I think it is one of the things that the President's plan is trying to address. I think it will do it in a way—through the mandate, that forces that issue in a way that business will not in many cases be able to afford. I think what the Cooper plan is trying to do is to deal with that in another way that is far more sensible. I think other plans would do likewise.

I want to address the question, though, of the tax equity here. The Republicans debated the question of putting caps on deductibility long and hard; and I thought at one time we had basically adopted it. It was pretty much a 50/50 kind of thing if I recall.

If a bunch of Republicans are 50/50 on the equity of that, is anyone suggesting that more liberal Members of the House are going to be otherwise? I can't imagine that, and yet that is what is being said here; and I think it is being said here because the Clinton plan makes some major concessions to some major powers in the United States, the special interests that he decried in his speech the other day, that are let off the hook in this bill.

These are plans that perhaps have an average cost in the neighborhood of \$10,000 per capita, when the President's plan itself only assumes a guaranteed benefit, as they priced it, of about \$1,950 per capita which, when totalled actuarially, is probably 30 percent under what is really true. So the tax cap is really a question of equity.

If you are going to shift resources to subsidize people up to 200 percent of poverty, which I favor, then there has to be some tax equity in this; and the tax cap equivalent to the average cost of not the lowest cost necessarily, but the average standard basic cost of coverage is the equitable thing to do. I am willing to support that, and I wish it had been in the Republican package, and I support it in the Cooper package. It has to be a part of any plan; otherwise you are going to tax somebody else.

The President's plan taxes small business. If you are forced to go into a regional alliance, which 88 percent of the work force is going to be, you are going to be forced to pay a much higher price, and that is going to be more onerous than what we are suggesting here in tax equity.

Having said that, I think there is a problem I have with the Cooper bill that I have been trying to maybe consider getting some changes to; and that is the whole issue of mandates on business. We are not talking about forcing them to pay, we are talking about requiring that they provide access, which is different. That is in the Republican bill.

I want to put the question to you, why not individual mandates and individual subsidy, as opposed to business subsidy, because then that choice rests with the individual; and with respect to the issue of tax equity, if you have an individual subsidy, then if an employer has someone below 200 percent of poverty, then the subsidy can go to the individual and offset the effects of the tax cap on the other end. That is a far more equitable way to deal with it.

I know that you have addressed this question, and I would like to hear an explanation as to why not build into your plan an individual mandate and an individual subsidy that even adds more flexibility and choice to the system?

Mr. COOPER. The individual mandate is an appealing notion and is in the so-called Chafee bill. It has three major drawbacks.

First, it is probably difficult to enforce because even auto insurance is tough to enforce;

It is probably expensive, because the level of subsidies may be very great in order to entice the individual to buy coverage he would not otherwise buy;

Third, you have a problem of possible employer dumping. If they know that the employee would have to buy a policy anyway and they don't have to provide it, some unscrupulous employers may shirk their responsibilities.

Perhaps those problems may be overcome. They have limited my interest in that approach at this point.

Mr. McMILLAN. On the question of unscrupulous employers, I think that if they are unscrupulous, they will be unscrupulous with or without health care reform. What you do is provide an avenue for that individual who does not have access to good coverage in a corporate plan to come into the HIPC and enter into their agreement. If they have individual mandate and individual subsidy, they take that subsidy with them and into your managed care approach.

Mr. GRANDY. The point, rather than mandates, is empowerment. We discussed this when the coalition was formed as to whether we wanted mandates to come before markets, and the decision was, no, let's see who does line up to join the HIPC.

The other thing we do agree on with the Clinton plan—and I think will prevail at the end of the day—is an employment-based system. I think that has worked well in this country, and I think part of that is that individual mandates notwithstanding, most Americans, when it comes to health care, love choice but they hate choosing. In other words, they don't necessarily want all of these plans laid out in front of them. And even though we are trying to win them into perhaps more consumer-wise behavior, I am not necessarily sure that an individual mandate up front would give them that learning curve that they need to get into the system.

I think it is safe to say that those of us in the coalition—and we are working with folks in the Senate, particularly John Chafee and the authors of his bill—to kind of split this difference. It is not something that we would say, no, we will never agree to that. But I do think it is worth saying that government can always impose mandates. We do that very well. But it is something else to allow a market to go forward and then reassess in 3 or 4 years and see if the people Mr. Kreidler talked about are not in the system and if we have to mandate them to be in the system to lower costs.

Mr. WAXMAN. Thank you.

Mr. Dingell.

Mr. DINGELL. Thank you, Mr. Chairman. I am delighted to see our two colleagues here and want to thank them for being here to assist us in our consideration of the matter.

I was interested in the financing mechanism. I gather that is essentially going to be a tax cap on benefits; is that right?

Mr. COOPER. We have two basic ways of funding our proposal. One is a tax cap; the other is smaller Medicare savings than the President proposes.

Mr. DINGELL. You say, smaller Medicare payments than the President proposes?

Mr. COOPER. Smaller savings from the Medicare program than the President proposes. He asks that we cut Medicare by \$124 billion over 5 years; we ask that it be cut by \$40 billion over 5 years.

Mr. DINGELL. As I read in the bill at pages 17 and 195, the tax would begin at the lowest cost premium; is that right?

Mr. COOPER. That is what we suggest because that is the toughest cost-containment if you are interested in cost-containment.

Mr. DINGELL. What would the lowest cost premium be? How would you define that?

Mr. COOPER. The health plan would have to prove it was solvent, that it was capable of serving a fair slice of population in a region.

Mr. DINGELL. I am trying to understand something. You said that it would begin at the lowest premium. It says the term "reference premium rate" means with respect to an individual residing in an HIPC area with the lowest premium. So, in other words, does that mean that anybody who was paying higher premiums than the lowest premium in the area would begin to pay a tax; is that what that says?

Mr. COOPER. The goal of the provision is to make all the health plans compete on a level playing field whether they are an HMO, PPO, IPA or regular service competing for a fair slice of the population.

Mr. DINGELL. Let me try and recast the question.

The bill says the term "reference premium rate" means, with respect to an individual residing in a HIPC area, the lowest premium.

Am I fair in inferring that any employer who was paying more than the lowest premium would begin to pay a tax?

Mr. COOPER. It would have to be a federally defined benefits package. It would have to be at least the Federal standards, and there would have to be a competitive bidding process for bidding to see who could offer it at the lowest price.

Mr. DINGELL. Where would these Federal standards be defined?

Mr. COOPER. A national standards setting commission appointed by the President and approved by the Senate.

Mr. DINGELL. Would these all be HMO's or PPO's or freedom-of-choice plans?

Mr. COOPER. They could be any delivery system—HMO, PPO, IPA, POF. They could be fee-for-service, indemnity medicine as well.

Mr. DINGELL. Well, I am trying to find out at what level the tax benefits would kick in. You said that the commission—you had set up, I note, at another section in the bill a set of boards and commissions at page 122. What would be the function of each of these boards?

You set up a health standards commission. I gather that that is going to recommend to Congress, according to the language, a uniform set of effective benefits to apply under this title for 1995 and subsequent years? Is that the function of this body?



Mr. COOPER. We want everybody in every State to know what the minimum standards package is and never has been a package that is worse than that. This would be a good package put together by health professionals, not by politicians. We would vote on it, yes or no, without amendment, using the base closing mechanism; so it would not be a politicized package.

Mr. DINGELL. If we reject that, what happens?

Mr. COOPER. I guess the health standards commission would have to go back to the drawing board and draw up another package.

Mr. DINGELL. Is that set out in the bill?

Mr. COOPER. Yes.

Mr. DINGELL. Where?

Mr. COOPER. If we use the base closing procedures, Congress is free to—

Mr. DINGELL. The base closing mechanism, as I recall the recommendations, if rejected, simply ends it; and the commission was not required to come forward with a new set of recommendations.

Mr. COOPER. I believe, beginning on page 101, we explain the procedures; and the intention of the authors of the bill is to have them go back to the drawing board.

Mr. DINGELL. What we are dealing with here, is the language of the bill and not the intention of the authors. Where in the bill would they be required to come forward again and bring in a new set of recommendations, if the Congress rejected them?

Mr. COOPER. I would be happy to supply that. Top of page 108, treatment of disapproval.

Mr. WAXMAN. Mr. Dingell, your time has expired.

Mr. DINGELL. I am sorry, Mr. Chairman. I was thoroughly enjoying this.

Mr. WAXMAN. We will let you have a second round. We want other members to have a chance for the first one.

Mr. Hastert.

Mr. HASTERT. Thank you, Mr. Chairman.

Mr. Cooper, you have been working on this issue, as have I, as has your colleague, Mr. Grandy, for a number of years, trying to find solutions to problems. I don't want to lead you on, and I want your answers to be as precise as possible, but you base your system on the system that we have in this country that employers basically pick up the cost of insurance, is that correct, or part of that insurance?

Mr. GRANDY. I am sorry. Mr. Cooper was reading the bill. The answer he would have provided, had he been paying attention, was, yes, we do base it on an employer-based system.

Mr. HASTERT. Is that promise that probably—and we have varying statistics—that 85 percent of the people in this country already have insurance from an employer based—so Mr. Wyden's assertion that most of the people like the system that they have now is based on most of the people like the system that employers pick up a good part of the bill.

Mr. GRANDY. Voluntary employer coverage paid, or copaid, has basically produced that figure, 85 percent coverage.

Mr. HASTERT. If you take that one step further, the problems in this country maybe are marginally on those companies that pick up

employer costs on health care, but more often, they are on groups of people who don't provide health care insurance. That is where the real problem is, isn't it, in this country?

Mr. COOPER. Thirty percent of the uninsured in America have no contact with an employer at all. They are not employed, or they are students or have no contact. They vary in their characteristics. A full 30 percent are not, in any way, in the labor market.

Mr. HASTERT. A number of the uninsured are under 26 years of age; a lot of them are between jobs. A large number are self-employed or work for companies under 50 or under 100.

Mr. COOPER. That is correct.

Mr. HASTERT. Basically, one of the things that—I think there are three premises out there that the President wants to cover, and I think most of us want to cover; we want to make sure that we can hold down health care costs, and there are provisions in all three bills that do that. Is that correct?

Mr. COOPER. That is correct.

Mr. HASTERT. We also want to give people portability, health care security, and take away the problem of preexisting conditions; and you do that?

Mr. GRANDY. Absolutely.

Mr. HASTERT. The other issue is, how do you get to that number of people out there that don't have access to health care insurance today; and because they don't, they still go to the hospital, they still are in automobile accidents, and the cost is shifted to other people. A large part of those people are either part-time employees, working for small businesses—tell me if you think I am wrong. Don't a lot of those people have to go to the market and pay 150 to 300 percent of the cost of insurance that somebody working for a bigger company—I am talking about a couple earning \$30,000 in a mom-and-pop grocery store and they have to pay \$9,000 if they can get it.

Mr. GRANDY. That is correct, and if they have one event, they will likely lose their policy next year.

Mr. HASTERT. So the issue is how to get those people on board, right?

Mr. GRANDY. That is exactly what the Cooper-Grandy bill tries to do, Mr. Hastert. We are trying to change the acute care portion of Medicaid so that we do capture those low-income individuals, usually in minimum wage jobs, and allow them to buy a policy that they can keep; and two, to allow small employers the same kind of purchasing power that a large corporation with a lot of employees has. That is the whole purpose behind the health care purchasing cooperative.

Mr. HASTERT. So there is a commonality of purpose across the board in all health care plans out there, especially ones that are based on employer mandates; that is, we are trying to help people who don't have the ability to help themselves today because basically they are priced out of the market.

Mr. GRANDY. We want to give them the tools to exercise the right of access to health care, but we want them to exercise their responsibility—

Mr. HASTERT. At the same time you don't take away the health care of 85 percent of Americans who have health care and basically like what they have?

Mr. GRANDY. We don't try to drastically alter what they have, either. That argues for the smaller threshold in the Cooper-Grandy bill than the 5,000-employee threshold in the Clinton bill.

Mr. COOPER. The gentleman is correct. Most Americans are relatively satisfied with their current coverage and with their current doctor, and we try to preserve what is good in the system and we try to root out what is bad.

Mr. HASTERT. So basically most Americans have high quality health care, choice of where they can get that health care; and being able to get the health care without being rationed is important. What you are trying to do is to take the other group of Americans that don't have that right and give them that right also; is that correct?

Mr. COOPER. Exactly.

Mr. WAXMAN. Thank you, Mr. Hastert.

Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman. One quick question and I will yield to the chairman.

Mr. Cooper, doctors you talk to anywhere in this country are frustrated under the present system with insurance companies looking over their shoulders and second-guessing them and saying you can't do this or you can't do that.

That has saved the system money and kept doctors from doing procedures they should not have done. However, it contributes to the feeling that physicians have that it is not much fun to practice medicine anymore, and they are not as good for their patients as they could be if they didn't have these insurance companies looking over their shoulders.

Isn't your proposal only going to exacerbate that? Won't there be more of that and more pushing prices down and second-guessing and insurance companies performing that way?

Mr. COOPER. I would disagree with your assumption that the current system has really saved us money. As IRA Magaziner puts it, today we have checkers checking checkers. We have HCFA employees who will never see the patient, who are second-guessing surgeons. We have insurance company employees who are doing the same thing. We are trying to shift regulatory paradigms so it is no longer please the bureaucrat, please the great unseen reimbursers. It is, please the patient, do an excellent job of treating your patient; and any paperwork requirement should be focused on patient care, not reimbursement.

We think we have an opportunity to restore sanity to the system. It has gotten completely out of control, because right now the reimbursement decision is completely separated from the patient. It is a long distance transaction where the reimbursers who sometimes are not medically trained will be second-guessing highly trained people.

We try to shift the entire regulatory approach. The fundamental change of the Clinton administration adopts a great deal of that thinking. We want to try to put power in the hands of people who are actually providing the care, so they will have the maximum in-



centive to do the best job of serving the patient, not pleasing the reimbursers.

Mr. WAXMAN. If the gentleman will yield, you don't think managed care or HMO's save dollars in delivery of health care?

Mr. COOPER. I think they do, at least initially. I think once HMO's are in place in today's shadow-pricing environment, sometimes they are tempted to copy the behavior of fee-for-service providers.

There seems to be an initial savings at least.

Mr. WAXMAN. The explanation we have heard day after day in these hearings is that one of the reasons we are seeing some drop in expenditures for health care is because employers are turning to managed care HMO's and they are saving dollars. They can save dollars through greater efficiency and also by denying people care, which is a great concern.

This is the 20th hearing we have had on health care, particularly with regard to the President's bill. We have had hearings on special population groups. If you have a disability, you don't want to be forced into an HMO that doesn't have somebody who knows how to deal with your disability.

We had a hearing on essential providers, the only ones available in minority communities or rural areas. We had a hearing on alliances, we had a hearing on the role of the States, employers' responsibilities. This is the first hearing, I believe to be the case, in any congressional setting on your proposal; and let me submit to you, your proposal is not a modest one.

Your proposal is a radical one, because your proposal, it seems to me, is going to take us on an experiment of social engineering which, according to Mr. Grandy, would have people have a learning curve to shop for health insurance. I think a lot of Americans will not be happy to be on the learning curve to shop for health insurance because they are going to be forced into the lowest-priced HMO, or they have to buy out of it and learn how to do that.

How do you respond to this charge that I am making that people are going to be losing what they already have, be forced into the lowest-priced HMO because that is all they can afford? Aren't you empowering people only to what they can afford, and what most will be able to afford is only the lowest-priced HMO and nothing more?

Mr. COOPER. With all due respect to the Chair, I would have welcomed an earlier hearing on the bill.

Mr. WAXMAN. What is your answer now?

Mr. COOPER. I felt as if my bill were being scrutinized even in prior hearings.

Mr. WAXMAN. Do you think that wrong to scrutinize your bill?

Mr. COOPER. No. I would have welcomed earlier scrutiny of our bill.

Mr. WAXMAN. We still have time.

Mr. COOPER. The chairman and I, I think, disagree on the role of government. The chairman has a long and distinguished career in health care reform. The chairman has usually preferred larger government solutions to problems than I perhaps do. That is not to fault the chairman. You have your own views. I tend to be more of a new Democrat, focusing on smaller government solutions.

Mr. WAXMAN. You are also a younger Democrat. Thank you.

Mr. Hall.

Mr. HALL. Thank you, Mr. Chairman. I have a problem with new Democrats and young Democrats. I would start by saying to Mr. Cooper and Mr. Grandy that I appreciate the time they have put into it.

Mr. Grandy certainly makes sense to me on the abortion issue, leaving it where it is. It is another battle that could sink health care for this country.

Mr. Cooper, you have represented the Congress well, the House well and this committee well. Sunday morning while we were warming up for the Super Bowl, getting ready for it, I watched you and Mr. Rockefeller. You handled yourself well there. I don't know how you stay around Rockefeller for 30 minutes and don't ask him for money, but you didn't even do that.

I have a complaint about the timetable we have set here. I don't have a right to complain because I have not attended every session we have held, but I have had someone who knew more about it in attendance, telling me what was said. I think we need probably more time to work with this subcommittee and more input into this subcommittee.

I think we are also fortunate to have Chairman Dingell, who is a congenital anomaly, caring about health. His father before him had a plan and a goal and a dream. I think in Chairman Waxman we have one of the most knowledgeable people in the area of health care.

I think we are going to get a fair shot at it, but I hate to see us telescope it into a time limit when we have to have something to the Floor, because we can make mistakes. We made a mistake on catastrophic; we didn't really know who paid there until we passed a bill, sent it out, and had to come back and redo it. Our projections are not too accurate.

In 1965, if you remember, when health care expanded to the elderly, the government made a prediction that \$9 billion would be the cost for Medicare, and in 1990 it was way over \$100 billion, \$9 to \$106 billion; and Medicaid, their estimates were a billion dollars back in 1965 for Medicaid, and it is \$75 or \$80 billion.

So we have heard projections, and most of the speeches I have heard talk about projections. Until we can add and subtract and listen to life testimony presented here, I don't see how we are going to get to that by the schedule that is laid out.

I hope we don't pass this simply because somebody can get 216 votes. I hope it is well thought out. Thank you for the time. I am not on either bill, but I am willing to listen. I believe that if we pass a bill that doesn't make sense, that won't fund it properly and fairly, it will fall and the very people we are trying to help, the little people in our society, get hurt worst.

My fear and your fear of being forced into an early vote with the result that maybe we don't have any bill until we get down to September or October and then say the do-nothing Congress has done nothing, so we will go to single-payer, we are going to nationalize it—which would be the worst thing to happen—that is something none of us wants.

So I guess my question would be on the major issue, which seems to be coverage—how we are going to cover everybody; and there is a difference in universal access and universal coverage, and most of us want universal coverage. We have universal access now if you just have the money.

Notice in the ads—sometimes for antique cars they say, restorable—it might be two wheels and an engine—and if you've got enough money, you can restore it; and the health situation is the same way.

Mr. COOPER. I have the highest regard for my friend from Texas, and I was delighted to provide him with pregame entertainment because you are my favorite Dallas Cowboys fan.

This may be the biggest job this subcommittee has ever been asked to do in its history in 1 month. But we have to tackle these issues. The September-October timetable is tight, as well, for the entire Congress. If we work hard enough, we can do a good job on these bills. The Governors have already helped show us the way.

Mr. GRANDY. One of the reasons this bill is before the committee today is because we believe this is a bill that we can enact. I can't make the same conclusion about the Clinton bill.

I serve on the Ways and Means Committee. We will have extensive deliberations, and we haven't even gotten to the judicial portions that will be included in any package. I think we have to intensify the debate, even if we don't decide, because one of the effects we are having on the private sector, whether it is a pharmaceutical company or groups of physicians, is reducing the inflation factor in the health care marketplace.

Sometimes the threat of what government is going to do to you, rather than what we actually do for you, drives the private marketplace to make voluntary price restraints, which is one of the reasons we have seen a slowdown in health care costs. I would not want to concede that advantage right now. I am in no hurry to pass a bill that I am not comfortable with, but I think this Congress, particularly with leadership like the chairman of the subcommittee and the leadership of the chairman of the full committee and people on Ways and Means and elsewhere, are capable of doing this.

I don't want this to become too gradual a discussion, because I think we are capable of discussing this now and reaching some conclusions; and the more we do that and the more members participate in this debate, I think we will have informed decisions and not political ones.

Mr. HALL. I thank the chairman.

Mr. WAXMAN. All members have had a opportunity for a first round. I will recognize members for a second round, and I am going to start.

Mr. Cooper, I want to apologize. I have the highest regard for you, and you are an important and esteemed member of this subcommittee. While we are looking at this bill, we have looked at other aspects of the problem, on other issues, and we need to look at all these issues very carefully because we are looking at a reform that is going to be a major piece of legislation.

While I am asking questions here, we will have to have a lot of other conversations as well to understand differences and where we can bridge those differences, and I look forward to that.



I do want to get factual information on the record.

You would cut \$40 billion out of Medicare. What would you do with that \$40 billion you cut out of Medicare?

Mr. COOPER. Our proposed slowing of the rate of growth of Medicare is a small fraction of what the President proposes, and we would take that money and use it to primarily help fund the new Medicaid program.

We repeal Medicaid and start again with a new program for the poor and the near-poor.

Mr. WAXMAN. As a subsidy for them to be able to purchase health insurance.

Unlike the Clinton plan, you wouldn't provide benefits for prescription drugs or some advances in home health care; is that correct?

Mr. COOPER. Incorrect. We have a prescription drug benefit. It is in our system. We would invite seniors to join our system. We have new preventive care services, lots of different things, because we feel that Medicare has not been strong enough on the various preventive services. We are interested in adding other things.

My bill was first introduced some 3 years ago, and various long-term care issues were not really on the table then. I am very intrigued with the President's home health care benefits for the disabled. We may be interested in a separate bill to add those to this piece of legislation.

Mr. WAXMAN. You take \$40 billion out of the Medicare program. You still leave a Medicare program; you don't eliminate Medicare, do you?

Mr. COOPER. The chairman knows the answer to that question. We do not fundamentally change the Medicare system at all.

Mr. WAXMAN. You said the elderly can sign up in other plans. They would have to voluntarily give up Medicare and go into these plans?

Mr. COOPER. They would use the Medicare benefit to enroll in the same plan that their kids or grandkids belong to, if they choose, an entirely voluntary decision on the part of Medicare beneficiaries.

Mr. GRANDY. If you do enroll in some kind of a managed care option, then a prescription drug benefit would be part of your basic plan.

Mr. WAXMAN. I ask you because I am trying to understand it. I am not trying to goad you, but would be interested in exploring further how you take a Medicare benefit and trade it in.

I want to ask you another question. If you eliminate Medicaid, instead you replace it with a subsidy for people who are below 200 percent of poverty on a graduated scale, those close to 200 percent get less, those at the bottom get full subsidy. While you repeal Medicaid, you also repeal the Medicaid part which pays for nursing home services for long-term care. Was that your intention?

Mr. GRANDY. No, Mr. Chairman. We do not repeal the long-term care portion, just the acute-care portion.

Mr. COOPER. The chairman is well aware of the problems of the current Federal-State matching system of Medicaid. The chairman is also aware that there may be a new and better way to divide

that responsibility because we are tired of unfunded Federal mandates, and we are tired of State gamesmanship.

We want the Feds to pick up 100 percent of acute Medicaid costs. We want the States to begin acquiring responsibility for long-term care for the Medicaid population. We think that is a fair way to divide the pie, because there would be accountability.

Mr. WAXMAN. You are offering an idea for us to consider. Your bill repeals title XIX. Title XIX is all on Medicaid. In repealing all of XIX, you repeal the program that pays for long-term care. Mr. Grandy said you didn't.

You said you would like to have something to give the States more responsibility, but you don't do it in your bill. That is at least my reading of it. I suppose we can make the bill say what you want it to say later, but it doesn't say that now.

Mr. COOPER. The chairman knows that for several years we have stated our intention to divide the pie as I just discussed with the chairman. The Chairman is the world's leading expert on today's Medicare programs—

Mr. WAXMAN. The chairman reads the bill and the bill says title XIX of the Social Security Act is repealed. That is page 2.2, line 16. I only know what I read. I know I should know more, but that is all I know.

Mr. COOPER. States would acquire responsibility for funding the long-term care portion for Medicaid. I would be happy to work with you and Legislative Counsel Ed Grossman, who helped us with the drafting of our bill.

Mr. GRANDY. One point on the long-term care. I can't let it stand that we want to repeal long-term care; we do not want to repeal long-term care. Not only do we give States control over long-term dollars, we have more long-term care dollars flowing in than acute dollars.

We have a transitional benefit that flows in over 4 years to help States manage the costs, but we give them more control to create community-based care systems which many States—

Mr. WAXMAN. Do you give them dollars or do you just give them the responsibility?

Mr. GRANDY. Dollars to go with it. It is an authorized amount; is it not? It is a transition program Mr. Chairman.

Mr. DINGELL. Mr. Chairman.

Mr. WAXMAN. Mr. Dingell.

Mr. DINGELL. I am comforted to hear the intention, but I am just curious, where would you replace the language which relates to long-term care in title XIX of the Social Security Act? How would that program and how would those moneys and what authorities would you have to replace those, the loss of the authorities and the requirements of title XIX?

Mr. COOPER. If I may answer the chairman's prior question, on the bottom of page 107 and the top of page 108 is the answer to your question about what would happen if the Congress disapproved the health standards committee recommendation. They would have a period of about 15 days to respond. That was just in answer to your prior question.

Mr. DINGELL. I am delighted about that.

Could I have an answer to this question?

Mr. COOPER. If the chairman would give me a minute to try to find the answer to your second question.

Mr. DINGELL. Is the question important?

Mr. COOPER. It is extremely important, and I look forward to questioning the chairman on his bills in the future.

Mr. WAXMAN. Let's move on. Let me advise you that this bill certainly is not law yet, so we can make changes in it. You do repeal title XIX. As I read it, that repeals the grant of Federal dollars under Medicaid for nursing home care and also repeals all the nursing home standards that we enacted to try to make sure those nursing homes live up to those standards.

I gather you have not quite the intent to do that, and that is my point.

Mr. Greenwood.

Mr. GREENWOOD. Thank you, Mr. Chairman. I would point out that if the gentlemen, Mr. Cooper and Mr. Grandy, don't have all the answers at their fingertips to every question, they should not feel bad. After 20 hearings with administration officials, it is clear that the administration also lacks answers by a wide margin.

I would like to talk to you about the health insurance purchasing cooperatives (HIPC's). One of the concerns raised about your proposal is how the premiums paid by particularly small businesses will compare to the premiums that they are paying now.

As I understand the HIPC proposal in your bill, we would bring the Medicaid population into the HIPC and we also would mandate that employers with fewer than 100 employees be a member. They would not necessarily have to pay for the health benefits, but if they do provide them, they have to obtain them through the HIPC.

Explain to me how confident you feel that those risk pools would be large enough particularly given the higher-than-average risks in the Medicaid population, so as not to cause employers to find higher rates there. If, in fact, employers with fewer than a hundred employees find that they can acquire health care elsewhere at a lower premium elsewhere, would your bill permit them to do that?

Mr. COOPER. There is a trade-off. You do not want an unbalanced risk pool at all, at whatever level. There are trade-offs. You don't want giant health purchasing alliances either, so you have to pick a number and there are no magic numbers. It depends on solid actuarial data in each region of the country, and it will vary somewhat.

So we are anxious to work with committee staff, with OMB and CBO and other experts, to help us find the right balance, because without balanced risk pools, you will not have a system that functions effectively. You will not have the right community rating.

Our purpose is in no way to penalize providers who see the poor or uninsured. Those folks should be rewarded, because we do not want any health plan to see the young and wealthy exclusively. Any health plan should be seeking out a fair share of the Nation's population. That is the best way to spread risks in society and to make sure that doctors and hospitals are really treating the population, not just the privileged among us.

Mr. GRANDY. To kind of put the Cooper-Grandy bill in the greater managed competition cluster, which probably includes the Clinton bill on the left and the Chafee bill on the right, the reason we



mandate cooperatives for employers with a hundred or less is two-fold. One, we thought 5,000 was too great a number; and two, we did want to address the concern of these high risk, usually Medicaid or within-200-percent-of-the-poverty-line individuals who could conceivably drive up the cost of the pool.

Under a cooperative model, there is no protection for these individuals. They can buy in but they don't necessarily have the purchasing power that they would in a mandatory cooperative; or if you do get the ability to deliver health care services in that area competitively, you must take these people. Will they drive up the cost to everybody else? We don't know that yet because we have not specified exactly how big these pools are going to be, and we don't think we should. That is an attempt to let the marketplace work itself.

The one place where there has been some experimentation with this, that we have seen prices go down to small businesses and to Medicaid populations, is the bill that California enacted last year, which is a voluntary purchasing cooperative. It is probably more successful in California because California has a longer and more successful record of managed care models.

We believe that with competition for these regions by competing health purchasing cooperatives and with the knowledge that you must cover everybody in that service territory, price will go down and people who up to this point have not been served will find themselves in a price they can afford. Don't forget that these folks, even if their employer is picking up not one penny of the premium, can deduct 100 percent of that premium whether they are self-employed or working for somebody else, and that would be in addition to a subsidy for a low-income individual.

Mr. WAXMAN. Mr. Dingell.

Mr. DINGELL. I want to pursue further the way the benefits would work and how the taxes would come into play. I believe we have come to an understanding that the commission would recommend a level of benefits in a plan; is that right?

Mr. COOPER. The national standards setting commission would come up with a federally defined basic benefits package below which you could not go.

Mr. DINGELL. And any plan which afforded a higher level of benefits would then be subject to tax?

Mr. COOPER. I think the chairman is using the word "tax" in an overly broad sense. We do not touch the exclusion. We would limit the corporate ability to deduct so-called "Cadillac plans."

Mr. DINGELL. So you tax the corporation that offered any benefits that were higher than that; is that right?

Mr. COOPER. We would trim a currently available tax deduction.

Mr. DINGELL. But anything which an employer provided that was above that would be taxed?

Mr. COOPER. It would no longer be fully deductible.

Mr. DINGELL. What would that be?

Let's figure that they would fix that level of benefits. What I am trying to understand is, would that level of benefits be for a HMO or for a PPO or for a freedom-of-choice plan? If the lowest cost—because the language says the "lowest cost" or the "lowest premium"; that is precise language—if anybody paid more than the

lowest premium for that, that then would be subject to tax; is that right?

Mr. COOPER. The chairman knows the Detroit area has one of the highest health care costs of any region in the country and it is hard for me to predict with accuracy which plan what would make the best and lowest bid. It may be an HMO; it may be fee-for-service. You have a lot of flexibility in your area, as I understand it, since the margins are so wide.

Mr. DINGELL. So anybody that paid more than the lowest premium would find that the plan would be subject to the loss of a tax exclusion; is that right?

Mr. COOPER. Only a corporate tax change. The individual tax change is a new tax benefit that they have previously never enjoyed. It is good news for the average citizen.

Mr. DINGELL. I am trying to understand, when the corporation lost its tax exclusion, it would lose it on everything over the lowest premium; is that right?

Mr. COOPER. It is a tax deduction, sir, not an exclusion.

Mr. DINGELL. But the answer to that question, then, would be yes?

Mr. COOPER. Under our proposal. There are ways to modify our proposal if you are interested in less cost-containment. But, yes, under our proposal.

Mr. DINGELL. So anybody who was a beneficiary of a plan which paid more than the lowest premium which was defined by the commission would then find their employer would pay a tax on that?

Mr. COOPER. Their tax deduction would be trimmed.

Mr. DINGELL. So wouldn't this have the practical effect, then, of driving everything towards that lowest—as you use the words in the bill, the “lowest premium,” because the employer will be then under pressure to go down to avoid that tax; is he not?

Mr. COOPER. I had extensive discussions with the AFL-CIO on this issue. This is a friendly change to bring more equity and fairness to one of the government's most wasteful and ignored programs.

Today, some corporations can fully deduct benefits that are not really worth it.

Mr. DINGELL. I sense where you are going, because Mr. Grandy commented that too many have too much benefits, and I sense that this is an attempt by him and you to reduce those benefits.

I am quoting Mr. Grandy. These are not my words.

Mr. GRANDY. That is a quote that Everett Koop made.

Mr. DINGELL. I was so impressed that I wrote them down. You feel, I gather, that too many are getting too much benefits, so you are going to make some of those benefits subject to tax by their employer so as to reduce the level of benefits to those who are deriving the best benefits.

Mr. COOPER. Perhaps the chairman was absent during the first part of the hearing in which I stated clearly that we are adding a new \$54 billion program of tax subsidies for average Americans, so they can better afford benefits.

Mr. DINGELL. Where is that coming from? The money is coming out of the pockets of those who are getting a better level of benefits, that—as you would describe in your bill, the lowest premium.

Mr. COOPER. As I stated in my testimony, the money comes from trimming the corporate tax break.

Mr. DINGELL. Well, thank you very much for that. I want to try and understand, does this bill give universal coverage or does it not?

Mr. COOPER. Our bill can achieve universal coverage by the President's timetable of 1998, and it is our intention to achieve universal coverage by the President's timetable.

Mr. DINGELL. You say it can. Can you make the bald statement that it will?

Mr. COOPER. No one has a crystal ball, but I believe our bill has a better chance than any other bill in Congress.

Mr. DINGELL. If I said it would not, would you deny that?

Mr. COOPER. No one has a crystal ball.

Mr. DINGELL. So you don't know whether it will achieve universal coverage or not?

Mr. GRANDY. Mr. Chairman, the President doesn't know that about his own bill.

Mr. DINGELL. I am not talking about the President's, though. I am talking about your bill.

Mr. COOPER. Can the chairman show me a bill that comes closer to achieving universal coverage, other than the single-payer bill?

Mr. DINGELL. Let's talk about some other things.

Mr. WAXMAN. Mr. Dingell, your time has expired. If you want a third round——

Mr. DINGELL. I have enjoyed the first two greatly. Thank you, Mr. Chairman.

Mr. WAXMAN. Mr. Klug.

Mr. KLUG. Thank you, Mr. Chairman. We have talked about two of the three major disagreements between your piece of legislation and the President's plan. Mr. Hall pointed out the great concern we have about costs and the level of commitment to the Federal Government and the fact that we have done a very poor job of estimating. And to the degree that the President's plan is more ambitious and yours, more directly imbued with a sense of common sense, I think it is much more moderate and much more likely what we are able to achieve financially.

We have talked about some of the shortcomings in employer mandates and the fact that the President's plan in some ways, reflecting the same problems of Hawaii, cannot guarantee universal coverage because based on what the Census Bureau has taught us, a third of the folks that don't have insurance aren't connected to the work force on a regular basis, so you are not necessarily ever going to reach them with an employer mandate.

Let me talk about the last point of disagreement with the President's plan, and that is the role for the National Health Board, greatly expanded from the original Jackson Hole Model. The National Health Board under the Jackson Hole Model was essentially set up to help guarantee that Americans trying to make a much more intelligent decision for health insurance purchasing in the future would have a place to look at outcome statistics and quality.



Now we find, under the President's plan, a National Health Board which essentially has the ability to come in and nationalize a State plan if a local health plan—if a State has not met the guidelines from Washington.

Would you comment on some of the expanded powers for the National Health Board under the President's plan and why the Jackson Hole Coalition thinks those are too far reaching?

Mr. GRANDY. I would be pleased to comment on that.

That is a significant difference between the President's bill and our bill. The National Health Board is essentially an unaccountable group of health czars. At least, as I read the President's bill, the only criteria for being on the board is to have no background in health care. They would basically be presiding over a series of State-run monopolies that would basically be having up or down votes on what the level of premiums would be, whether or not a plan would be approved or disapproved.

The Health Care Standards Board that is envisioned in the Cooper-Grandy bill is to a large degree an advisory commission that recommends conditions for benefits. I want to stress this, because very often you will hear from various kinds of providers, are we included in your bill; and we don't specify exactly what providers should deliver the service.

For example, if you have lower back pain, you might want a orthopedic surgeon or you might want a chiropractor. We don't necessarily try to pick winners and losers. The Health Care Standards Board recommends the condition and then Congress votes on whether it should be in the package.

The health purchasing cooperative which is the regional delivery mechanism is closer to a rural electric cooperative or a farmers market than a large kind of State-run entity that would be doling out health care policies and setting premiums.

So the point here is that we believe that health care should be community delivered and locally accountable. That is why we try and build the system from the ground up, as opposed to from the top down.

I am sure we are all familiar with Senator Dole's and Senator Specter's interpretation of what the real devils in the details are between the top of the bureaucracy and the consumer in the Clinton health care plan. I haven't looked at it that closely, but the reason that we tried to make our Health Care Standards Board as small as possible is because we did not necessarily want to proliferate a system of bureaucracies that would begin to usurp local control. That is why our purchasing cooperatives are smaller and locally run and elected, and that is why our Health Care Standards Board is made up of health care policy experts that advise and are advised by subordinate councils on what to deliver, and at that point they get out of the way.

Mr. COOPER. Mr. Grandy said it very well. We do not want a big-government solution to these problems. We try to keep government involvement to the minimum.

Government is not the enemy. Government can do some things very effectively, but then government needs to get out of the way.

We think by establishing a level playing field and by not having an overly intrusive bureaucratic control mechanism, we will deliver

much higher quality and much more affordable care to the people. It is important to get the National Health Board right and not let it be a stepping stone like the Canadian system.

Mr. KLUG. Do I understand the President's plan correctly in that under the President's plan, Washington can say, Tennessee, we don't like the way you are doing business; we are going to run it?

Mr. COOPER. There are very sweeping powers granted to national authorities, including in a lot of seemingly technical areas. People are just beginning to understand the President's bill. It is quite a job since it is 1,364 pages long. Ours is only 292 pages, but that is still a giant bill by congressional standards. So we have a big job before us, especially given the timetable.

Mr. WAXMAN. Mr. Synar.

Mr. SYNAR. Jim, in an attempt to abate the schizophrenic treatment that you get around here from stick to carrot, let me try the carrot.

Thanks for cosponsoring the letter to Mr. Waxman and Mr. Dingell, advocating universal coverage. I think that is a very important statement on your behalf and those who support your position.

First of all, as has been outlined before, you do not define a specific benefit package, which very much troubles me, and I think as a fellow legislator, one whose admiration for you is second to none, we are really asking, without a defined benefit package, the American public to advise their Members of Congress on an issue without knowing really what they are getting.

Don't you have some kind of an obligation to at least outline what you think is within the parameters of a benefit package, not necessarily to score it, but to see how far you are willing to go on that?

Mr. COOPER. That is an excellent point. We are not averse to an interim benefits package, because people are entitled to know what they are getting. We want this package to be an excellent package. Our only concern has been whether politicians know anything about drawing up such a package.

Senator Lieberman used to be in the Connecticut legislature, and he tells the story of having podiatrists in Connecticut wanting jurisdiction of the knee, so the Connecticut legislature just gave them the ankle. That is the way politicians decide things.

There are very few members of this body—perhaps Dr. Rowland and Dr. McDermott and Dr. Kreidler are the exceptions—who can even look read one clinical study, much less go through the thousands that are required to understand what a first-rate benefits package is.

I am afraid that if we do the job, we will politicize it and we will respond to every lobby and special interest group in America, and it won't be a basic package.

Mr. SYNAR. How am I supposed to sell any package to the public unless I tell them what they are getting?

Mr. COOPER. Let's work together on an interim package, but let's also have a date to get politicians' noses out of it.

Mr. SYNAR. Are you prepared to at least outline an interim package, so we can know what you are suggesting?

Mr. COOPER. Yes.

Mr. SYNAR. Second, would that include reproductive rights?

Mr. COOPER. The Congress has voted on that issue more times than I can count. I think we will have to make that a separate issue and let our colleagues vote on it.

Mr. SYNAR. If I look at the two bills, the President's and yours, the real difference is the issue of mandates.

Let me ask you this. Is there common ground that we can move towards each other on this issue? Are there things that can bring us together over this issue, so that we could marry up what I think are really two excellent ideas?

Mr. COOPER. I have been searching for common ground on this issue for almost 3 years now. I hope that we don't make the President's job harder than it is already, because in his State of the Union speech he never mentioned mandates. He could have, he did not.

The phrase he used was, hear me clearly; if you do not guarantee every American private health insurance that can never be taken away; then he went on to say, he would veto the bill.

He said, hear me clearly. We need to listen. The only veto threat in that statement was toward the single-payer bill, which happens to be the preferred approach over time of many of the members of this subcommittee. But many of us don't listen; so we are trying to find a way so the word "guarantee" can really mean what the President intends.

I don't think he meant a giveaway program. I don't think he meant a free lunch. I don't think he meant coercion. He could have used the word "mandate," but he did not.

Mr. SYNAR. Is there any bridge that can be built where there is mutual cooperation by business and individual employees on any kind of schedule that you would consider?

Mr. COOPER. I am happy to entertain any idea. So far, I haven't been persuaded that an employer mandate makes sense. I am still interested in looking at employer or individual mandates, but we think no mandate is a correct approach, realizing that the President is not for universal coverage immediately. The President is for it in 1998.

Mr. SYNAR. So are we talking about the difference being in the schedule of the approach of application, or are we talking about the principle?

Mr. COOPER. The key thing is to make sure we have quality, affordable health care all over America without destroying jobs. That is the bottom line.

Mr. WAXMAN. Mr. Hastert.

Mr. HASTERT. Thank you, Mr. Chairman. There are some things I think we need to talk about where there is some commonality across the board.

I would like to go through—first of all, there are no employee mandates and there is a commonality with a lot of other plans; is that correct?

Mr. COOPER. No plan but the President's has the employer mandate in it that I am aware of.

Mr. GRANDY. The mandate to pay, though. Every bill has either a mandate to provide or an individual mandate to consume.

Mr. HASTERT. Your plan doesn't have any global budgets, right?

Mr. COOPER. No.



Mr. HASTERT. There is a always threat that health care is going to be rationed when you have global budgets, so you get around that.

Do you have price controls?

Mr. GRANDY. The price control is the tax cap, Mr. Hastert. It is a price control that limits deductibility. We have had significant discussion about that. But the point is it is a micro-price control, as opposed to a macro-price control, and it is not something that would be legislated or rescinded or modified by Congress.

Mr. HASTERT. Beyond that, they have a choice to do that; is that right?

Mr. GRANDY. That is correct.

Mr. HASTERT. When we talk about a benefits package, we have been working on legislation in this area. We talked about actuarial equivalent, having a separate board to do that; because actually some health care provisions that have to be on Indian reservations in New Mexico and maybe in cow towns in Oklahoma and maybe in Connecticut are very different, the needs are different. That is why there probably ought to be some type of a national equivalency, but an actuarial equivalent or somebody else making that decision, not politicians that want to put everything in, or everybody; is that correct?

Mr. COOPER. We try to build flexibility into our system not only by having health professionals draw up the package but also by having them specify conditions that should be treatable in a basic benefits package rather than prescribing treatments, because some people are going to prefer different treatments than others.

Mr. HASTERT. Is the choice theirs?

Mr. COOPER. Yes.

Mr. HASTERT. How about preexisting conditions? You say that no insurance company can really underwrite to prevent people from having preexisting conditions—

Mr. COOPER. That is true.

Mr. HASTERT. So that takes care of the continuity of coverage. Somebody can move from job A to job B and still have a choice of insurance or be guaranteed of insurance when they get there.

Mr. GRANDY. In that sense, it is health care that is always there.

Mr. HASTERT. There is commonality between the plans?

Mr. GRANDY. That is true. A standard benefit would basically be waiting for anybody who moved in or out of the workplace.

Mr. HASTERT. And other plans have that also; is that right?

Mr. GRANDY. That is true. I think that is one area that most plans agree on.

Mr. HASTERT. And there is no job-lock where you do these types of things?

Mr. GRANDY. No. You can be unemployed under this bill and get pretty much the same benefits.

Mr. HASTERT. Your plans and other plans that you have worked on, Mr. Grandy, there is almost a quasi-community rating; is that correct?

Mr. GRANDY. I would call it modified community rating under our bill. We do have provisions for age and geography.

I would also state, clearly you don't want a community rating that is so rigid you conspire against preventive health behavior. That is something that we want to empower in the bill, not impede.

Mr. HASTERT. In your plan that has commonality with other plans, there is guaranteed renewability also?

Mr. GRANDY. Absolutely.

Mr. HASTERT. How about real tort reform? Do you really get into making sure that medical malpractice doesn't drive health care costs by overutilization of a lot of different issues and there is a way that people can get relief?

Mr. GRANDY. Let me take a stab at this. I think I am the only nonlawyer on the panel here, but as you know, when we wrote H.R. 3080, we spent a lot of time going through antitrust and malpractice and tort reform and added some very tough provisions, not just on malpractice but also product liability. Many of those provisions went from the GOP bill into the Cooper-Grandy Coalition bill, and I think it is safe to say that of all the bills that have been scored and produced and are now before the Congress, this is one of the toughest, if not the toughest, malpractice component in any of the legislation.

Some colleagues that were on the Coalition had to swallow hard to agree to some of the limitations on damages and recovery caps that we have in the bill.

Mr. HASTERT. Administrative reform using vouchers to buy poor people into plans, expansion of community health care centers and rural health care centers—

Mr. GRANDY. All in the bill and all lifted from the GOP bill, and it comes from the Rural Health Care Coalition which both Mr. Cooper and myself and Mr. Stenholm were significant cosponsors or members of.

Mr. HASTERT. Thank you, Mr. Chairman.

Mr. WAXMAN. Mr. Grandy and Mr. Cooper, you have been here for a long time, and I appreciate the fact you have been willing to come here and answer the questions of the subcommittee. The fact it has taken so long to get through all the questions shows a sincere desire by members of the subcommittee to understand fully your proposal.

I want to express my sincere desire to work with you. You have taken on a task of trying to figure out some ideas that I think are worth a lot of careful examination, and we need to work together to produce legislation, because I think the American people want us to think through all these issues and try to work out ways to bridge differences on them.

I thank you very much for being here.

We have panels to follow both for and against this proposal. Because of some of the panelists' schedules, we will continue on, but I am going to call a brief recess of 10 minutes for obvious reasons, and then we can get on to the other panels.

[Brief recess.]

Mr. WAXMAN. We are going to continue on with this hearing. Our next panel includes a number of witnesses testifying in support of H.R. 3222, Sara J. Singer, a Special Assistant to Allen Enthoven, professors in the Graduate School of Business at Stanford University, on whose behalf she is testifying today. Donna Miller is the

Chief Executive Officer of the Memphis Business Group on Health. Anthony J. Cebun is President and Chief Executive Officer of Tennessee Managed Care Network, or TennCare, in Nashville. Bruce Atwater is Chairman of the Board and Chief Executive Officer of General Mills, Inc., in Minneapolis. Mary Jane England is President of the Washington Business Group on Health.

I want to welcome you all to our hearing today. I want you to know that your prepared statements, without objection, will be in the record in full. And what we would like to ask you to do is to limit the presentation to 5 minutes. We are not as nice to other witnesses as we are to Members of Congress so we are going to have to keep very strict time.

Mr. Atwater, I know you are very pressed on your schedule, so I want you to go first. I hope you will be able to stay for the questions. If you can't, we will certainly understand.

**STATEMENTS OF BRUCE ATWATER, CHAIRMAN, GENERAL MILLS, INC.; SARA SINGER, GRADUATE SCHOOL OF BUSINESS, STANFORD UNIVERSITY; DONNA MILLER, CHIEF EXECUTIVE OFFICER, MEMPHIS BUSINESS GROUP ON HEALTH; ANTHONY J. CEBRUN, PRESIDENT, TENNESSEE MANAGED CARE NETWORK; AND MARY JANE ENGLAND, PRESIDENT, WASHINGTON BUSINESS GROUP ON HEALTH**

Mr. ATWATER. Thank you very much, Mr. Chairman. I appreciate the opportunity to go first. I also appreciate the opportunity to testify. What I am going to do is cover three subjects. The first is General Mills' successful experience using market forces and incentives to control health care costs.

Second, I want to cover the fundamental principles of health care reform that are derived from our experience. And third, I would like to comment on our strong support for the Cooper-Grandy bill as the starting point for health care reform. This bill relies on the same market supports and incentives that have proved so successful in our own experience.

General Mills has 126,000 employees and is one of the 25 largest firms in the United States in terms of employees. Our employment is growing sharply. We added 19,000 new jobs in the past year alone, and more than 60,000 jobs since 1988. The businesses that we compete in are intensely competitive.

We have a very strong financial incentive to control all costs, including health care costs. We provide our employees with high quality, cost-efficient health care plans. In fact, our plans are an important motivator as to why some people join the company. We have had remarkable success in controlling health care costs.

Health care costs at General Mills are currently less than 5 percent of our payroll; 4.9 is the actual number. And our per capita health expense grew only 1.6 percent from 1991 to 1992, and is actually down from 1992 to 1993. The question is, obviously, how have we been able to get this kind of excellent cost containment.

We have used managed-care networks with a strong set of employee incentives for wellness and preventive care. In Minnesota in 1992, we helped found perhaps the most well-developed model of managed competition currently in the country. This plan costs 17 percent less than the HMO plan it replaced just 2 years ago.



In Florida, a similar alliance we helped establish has led to an actual reduction in the cost of health care for the entire Orlando area in each of the last 2 years. We have also given our individual employees incentives to control their own health care plan expenses. The amount of money that our employees contribute for their medical coverage is based on their fitness and lifestyle, as well as their actual utilization of our plans.

These employee incentives are big and they can reduce the cost of their contributions by more than 50 percent. This is a real factor in cost control, and is something that we would lose if employers and individuals were taken out of this business. Our hands-on experience in health care in Minnesota and Florida has led us to have strong opinions about what actually works and what doesn't.

We agree with President Clinton that all Americans should be able to get affordable high quality health care that can never be taken away. We agree that no one should be denied coverage because of a preexisting condition. No one should lose coverage because he or she becomes sick, changes jobs, gets divorced or whatever.

We also agree that persons with low and moderate incomes should receive Government assistance so they will not be denied coverage. All of the wrenching examples of personal hardship that the President cited in his State of the Union address can and should be taken care of by insurance market reforms. However, we also believe very strongly that competition and incentives, as we have shown in our own experience, deliver the highest quality health care at the lowest possible prices.

Individual and corporate incentives work. Regulation and bureaucratic mechanisms cannot provide an efficient health care system. A mandated approach that sets health care costs at a flat percentage of payroll destroys all incentives for both corporations and individuals to reduce health care costs. These mandates are the major problem with the Clinton administration's plan. The payroll tax is a tax on jobs. It would create a huge politically determined entitlement program on a scale never before attempted, financed principally by employer contributions.

Fixing an employer's maximum health care cost exposure at 7.9 percent effectively rewards those companies that have been the least efficient providers of health care while removing any employer incentive to manage costs below this level. Employer contributions at 7.9 percent will not generate sufficient income to cover premium costs. Government subsidies must fill this gap, but the gap is destined to grow rapidly because premium caps are tied to slower growing wages while premiums are tied to faster growing health care costs.

The result will be either an increase in the percentage of payroll limits on employer-mandated spending, or price controls or rationing or both. In Germany——

Mr. WAXMAN. Mr. Atwater, the rest of that statement is going to be in the record in full. But in order to be fair to all the witnesses, if you want to make a concluding sentence, but we are going to have to move on.

Mr. ATWATER. I guess our concluding sentence is that we feel this should be a bipartisan approach, as was said earlier, and as such, we support the Cooper-Grandy bill.

[The prepared statement of Mr. Atwater follows:]

**TESTIMONY OF BRUCE ATWATER****CHAIRMAN AND CEO OF GENERAL MILLS, INC.****I. INTRODUCTION**

I appreciate the opportunity to testify today. My testimony will cover three subjects. The first is General Mills' successful experience using market forces and incentives to control health care costs. Second, I will cover the fundamental principles of health care reform derived from our experience. Third, I'll comment on our strong support for the Cooper-Grandy bill as the starting point for health care reform. This bill relies on the same market forces and incentives that have proved so successful in our own experience.

**II. GENERAL MILLS' EXPERIENCE**

With more than 126,000 employees, General Mills is one of the 25 largest employers in the United States. Unlike many major U.S. corporations, employment at General Mills is growing sharply. We added 19,000 new jobs in the past year alone and more than 60,000 new jobs since 1988.

Approximately two-thirds of our sales are in the consumer foods business, while the remaining one-third is in the sit-down restaurant business. Thus, we are both a major manufacturer and a significant participant in the rapidly growing service economy.

The businesses that General Mills competes in are intensely competitive and we have a very strong financial incentive to control all costs including health care costs.

We provide our employees with high-quality, cost-efficient health care plans. In some of our businesses our health care plans are an important motivator to join the company.

As a result of innovative health benefit design and aggressive cost management, health care costs at General Mills are currently 5.6% of payroll in our consumer foods business and 4.3% of payroll in our restaurant business. Our per capita health expense grew only 1.6% from 1991 to 1992 and actually fell from 1992 to 1993.

The strategies we have employed to contain our health care costs emphasize use of managed care networks, with a strong emphasis on wellness and preventive care.



In Minnesota, where our consumer foods operations are headquartered, we helped found the Business Health Care Action Group in 1992, which is perhaps the most-developed model of managed competition currently operating in the nation. Internal calculations show that the plan offered by our group, with comprehensive benefits, streamlined administration and a strong emphasis on quality, with practice parameters developed by the Mayo Clinic, actually costs 17 percent less than the HMO plan it replaced just two years ago.

In Florida, where our restaurant business is headquartered, we helped establish the Employers Purchasing Alliance. This Alliance has led to an actual reduction in the cost of health care for the entire Orlando area in each of the last two years.

General Mills employees also have incentives to control their own health plan expenses. The amount of money employees contribute for their medical coverage is based on their fitness and lifestyle, as well as their actual year-to-year utilization of the medical programs. Those who strive for wellness and a more healthy lifestyle or are not heavy users of our plans can reduce the cost of their contribution to health care premiums by more than 50%.

### **III. PRINCIPLES OF HEALTH CARE REFORM**

Our “hands-on” health care reform experience in Minnesota and Florida has led us to have strong opinions about what actually works and what won’t. These experience-based principles of health care reform are outlined below.

#### **A. Universal Access**

We agree with President Clinton that all Americans should be able to get affordable high-quality health care that can never be taken away.

We agree that no one should be denied coverage because of a pre-existing condition. No one should lose coverage because he or she becomes sick, changes jobs or gets divorced.

We agree that persons with low and moderate incomes should receive government assistance so that they will not be denied coverage because they can’t afford it.

All the wrenching examples of personal hardship that the President cited in his State of the Union address can and should be taken care of by relatively simple insurance market reforms.

## B. Payroll Tax Mandates Destroy Incentives

We believe very strongly that competition and incentives will deliver the highest quality health care at the lowest possible price and that regulation and bureaucratic mechanisms cannot provide an efficient health care system.

A mandated approach that sets health care costs at a flat percentage of payroll eliminates all incentives for corporations and individuals to reduce health care costs. These mandates are the major problem with the Administration's plan.

The payroll tax is a tax on jobs. As proposed by the Administration, it would create a huge, politically-determined entitlement program on a scale never before attempted, which is financed principally by employer contributions. It constitutes a massive blank check issued by business to underwrite whatever the political system wants to grant its constituents in the way of health care benefits.

Second, as a political and economic matter, employer mandated financing cannot be passed without providing substantial subsidies for some employers. Under the Clinton plan, these take the form of "caps" on an employer's health care expense -- as little as 3.5% of payroll for small employers up to 7.9% of payroll for large employers.

Employer contributions at those percentages will not generate sufficient income to cover premium costs. Government subsidies must fill the gap. But this gap is destined to grow rapidly because the premium cap is tied to wages while actual premiums are tied to health care costs and wages can be expected to inflate at a far lower rate than health care costs. The result will be either an increase in the percentage of payroll limits on employer-mandated spending or dangerously-tight price controls on health care premiums and providers, which could result in shortages, delays, elimination of procedures and overall deterioration of quality.

Fixing health care costs as a certain percentage of payroll for all employers would change the relative cost structures of every employer in the country. It would also create winners and losers within and among industries.

Large manufacturers, companies with aging workforces, companies offering excessively generous benefit plans -- would reap huge windfalls as the government assumes significant portions of their health care liabilities.

Many manufacturers, with older, higher-skilled employees, pay 15% or more of payroll for health care benefits today. Under the Administration plan, that employer would see its costs reduced and capped at 7.9% of payroll annually. Who would pay the difference between the current cost and the new maximum payroll percentage? Other companies who have done a good job of health care cost containment and taxpayers.

Entire industries would lose. They include almost every low-wage sector of the economy, like child care providers and semi-skilled laborers. The entire service sector, the only part of the economy still reliably creating new jobs, could stall.

Industries in which low-wage, seasonal, or part-time jobs are common -- agriculture, forestry, fisheries, foodservice, hospitality, construction, retail trade, business and personal services, have higher-than-average numbers of uninsured workers -- would be hit hard.

Make no mistake, mandated employer financing will cost jobs. Many of these will be lower-paying service sector jobs with limited skills held by people who have poor prospects for employment in other sectors. These jobs represent their opportunity to climb the economic ladder. Employers who can will undoubtedly try to offset increased health care costs by cutting wages. But employers whose workers already have low wages do not have that flexibility. Their only recourse is to cut jobs.

It is ironic that many of those who should benefit most from health care reform will pay the ultimate price for universal coverage -- they will lose their jobs -- while those who should



benefit least -- large manufacturers and employees with bloated benefit plans -- will receive sizable, guaranteed, government hand-outs.

Finally, taxing employers and then subsidizing them to provide coverage for their employees is inefficient. It makes much more sense to target subsidies to individuals based on their income.

### C. Multiple Health Alliances Vital for Competition

Despite the fact that we qualify to run a corporate alliance and our health care costs are only 5.6% of payroll, we have concluded that the cumulative effect of the various provisions in the Administration's bill give us no alternative but to join a regional alliance and get out of the health care business. We have begun to inform our employees and their reaction has been uniform. They are appalled. The last thing they want is to get health care from a governmentally run bureaucracy. They will not look kindly on any plan that forces this result.

The reasons for our conclusion are varied, but I can assure you that many large companies, service and industrial, are reaching similar conclusions as they absorb the full implications of the Administration's plan. Let me explain why.

First, the Administration would impose a new tax, at least 1% of payroll, on any corporate alliance. This tax would consume much of the "savings" a corporate alliance might generate. And, because the revenue is being counted on to fund the remaining portions of the Administration plan, which is underfinanced, there is a strong likelihood the "price of the privilege" will increase.

Second, states are also granted unrestricted authority to tax corporate alliances further to pay for providing coverage. Since states are financially strapped, yet bear the responsibility under the plan for assuring universal coverage, it would be naive to think that corporate alliances would not be hit with additional state taxes for the privilege of remaining independent.

Third, the Administration plan does not allow an employer to join with other employers to manage costs. The driving force behind the best efforts to reform our health care delivery system,

initiatives like the Business Health Care Action Group in Minnesota and the Employers Purchasing Alliance in Florida, could be outlawed.

Fourth, because the regional alliances would dominate any local market (95% by most estimates), individual employer plans would not be able to compete against them with any hope of success; instead, costs would be "shifted" from the alliance to that employer, particularly when health alliance premiums are "capped." This problem only grows worse as more and more employers opt against running corporate alliances.

Fifth, employers would be forced to deal with various rules and regulations in each state in which they operate. Without ERISA pre-emption, states could compel employers to join mandatory single-payer systems.

Finally, employers opting for corporate alliances would forego the government "guarantee" of a fixed percentage of payroll for health care costs. Large employers with part-time workers, whom the plan requires to be covered by regional alliances, would forfeit the right to cap their premium expenses at 7.9% of payroll if they opt to cover their other workers in a corporate alliance. Such an employer could easily pay 90% of wages for health care benefits for a low-income, part-time worker receiving family coverage from a regional alliance.

#### D. Part-Time Employees

Large employers of part-time workers are seriously disadvantaged by the Clinton Plan. Part-timers are 19 percent of the U.S. work force-- a significant segment. Most part-timers want part-time work. They are students, young parents, second earners or older workers who want or need flexible schedules.

A part-time job is the first exposure to the workplace for many Americans. Such positions offer entry-level employment and training to those whose education and skill levels may not qualify them for other work. Part-time jobs also offer opportunity and upward mobility. The food service sector alone employs over 9 million people.

In the restaurant industry, 30 percent of restaurant management comes from the ranks of hourly employees, 70 percent of restaurant supervisors are women, and 20 percent are African American or Hispanic. One of General Mills' Vice Chairmen started as an hourly worker in one of our restaurants, as did the president of our Olive Garden chain, a \$1 billion business.

Service businesses employing part-time labor have low margins, and profits per employee are also low. The problem from a business perspective is weighing the economic value of a job to an enterprise versus the cost of providing that job. If the cost exceeds the value, the job is no longer sustainable.

Restaurant sales per full-time equivalent are only \$47,300 per year, while manufacturing sales per full-time employee are \$157,000 per year. Profits per service sector job are one-sixth of those in manufacturing.

Lowering direct wages to offset increased benefit costs in order to preserve the cost/value relationship is not an option with workers whose wages are already low. Price advances, the other option for covering increased costs, are extremely difficult in today's economic climate. And, under the Clinton Plan, price advances may be impossible, because our smaller competitors would be "capped" at a much lower cost, giving smaller businesses a competitive price advantage of up to 4.4 percent of payroll (the difference between 7.9 and 3.5 percent).

As previously noted, we have serious doubts that the premium caps-- which, we might add, do not take full effect for 8 years and are not available to us if we maintain a corporate alliance-- can remain at the level that has been proposed for very long if at all, yet they are the only thing standing between us and health care costs for our part-time workers averaging 35-40% of wages. We think the Cooper-Grandy bill's approach - subsidies for low-income individuals but no employer-mandated financing - is a far more realistic approach.

#### **IV. COOPER/GRANDY SUPPORT**

We are very concerned that health care reform not become a partisan matter. A bill this sweeping in scope, which profoundly affects our employees and impacts 15% of the economy, must reflect broad bi-



partisan consensus. It's fine for everyone to have strong views and to argue for them, but in the end we need to go forward with a plan that reflects consensus at the middle of the political spectrum.

Obviously this is another attractive feature of the Cooper-Grandy bill, but the point is larger than any one bill.

As more and more people begin to understand the full implications of various reform proposals on their own families -- our own employees are a good example -- the potential for divisiveness will rise. The cardinal tenet of physicians for many centuries has been "First, do no harm." The way to ensure that we do no harm is to avoid the extremes and find the broad middle ground.

Let me conclude where I began: Every American should be able to get affordable, high-quality health care that can never be taken away.

Achieving this does not require a highly regulatory, mandate-oriented, government-controlled program. It is neither the best approach, nor the only approach.

H.R. 3222 in our opinion, is a far better model for reform. The Cooper-Grandy bill neither creates nor relies upon government regulatory mechanisms to dictate health care delivery or constrain costs. It would restore responsibility and reestablish competition on the cost and value of care consumed. With equitable subsidies for persons who could not otherwise afford coverage, the Cooper bill would make high-quality health care available and affordable for every American.

The Cooper-Grandy bill is the starting point upon which to build a workable, bi-partisan solution to the health care problem.

Mr. WAXMAN. Thank you very much for your testimony.  
Ms. Singer, let's go to you.

### STATEMENT OF SARA SINGER

Ms. SINGER. OK. Thank you for allowing me to testify today. It is apparent that the traditional system has failed, both in terms of cost and access. It is failed primarily because incentives that it creates are all wrong. The fee-for-service system pays more for more, but not for necessarily better care.

This contrast, accountable health plans which integrate the financing and delivery components of the system, have an incentive to provide better care at less cost. We must rely on market forces to create a system in which informed, cost-conscious buyers, switch to the most efficient system because they see it in their own best interest.

Government can't accomplish this because it is rigid and inflexible. Even according to the administration's own assessment of the Federal Government, the Gore report, states in the name of controlling waste, we have created paralyzing inefficiency.

Both the Managed Competition Act of 1993 and the Health Security Act claim to rely on market forces. Although there is much in the Clinton plan with which I agree, the provision of universal health insurance, system reform through accountable health plans, and the call for outcomes analysis, quality measurements, and information reporting, the plan does not rely on market forces.

The Cooper plan empowers people with incentives, information, and subsidies where appropriate, to purchase health benefits on the basis of value for money. Clinton's proposal creates an entitlement that reduces responsibility for people to promote quality, cost-effective care. The Cooper bill limits tax free benefits at the price of the low cost qualified plan in an area. The Clinton plan includes no such limit, so it decreases the marketplace reward to health plans for lowering their price. This leaves market forces weaker than they could be.

Cooper limits the purchasing cooperatives to groups of 200, to test them first where they are needed most, and to leave a large private sector to ensure pluralistic demand. Clinton's regional alliances would include everyone, which would concentrate massive power in State agencies, easily turned into regulatory bodies.

The Gore report helps explain why this would be a problem. Federal monopolies receive their money without any direct input from their customers. Consequently, they try a lot harder to please congressional appropriations subcommittees than the people they are meant to serve. Cooper's National Health Board would have reasonable political insulation through which it would set and update a standard benefits package.

Clinton's National Health Board would be an arm of the executive branch and its benefit package would be set through the political process. Cooper's proposal makes a limited Federal contribution for low-income subsidies. The Clinton plan subjects the Federal budget to a large open-ended risk. With a 7.9 percent cap on employer contributions, the Federal budget must pay the excess if health care costs increase faster than wages. Plus, it is virtually impossible to predict the cost of windfalls to special interest groups.

Weak market forces due to lack of a tax cap, plus this risk to the Federal budget, force the Clinton plan to set overly ambitious cost containment goals, goals that not even the UK or Canada have met. Therefore, the Clinton plan will rely on price controls on premiums. But price controls don't work.

First, the incentives are all wrong. Health plans are rewarded for fighting regulations, not for efficiency. Second, it is politically untenable for regulators to force health plans to become insolvent so they won't do it.

Third, the fifth amendment forbids the taking of private property without due process and just compensation, including a fair rate of return to health plans. Furthermore, if price controls did work, quality and service would suffer. As Federal revenue requirements grow, the Clinton plan is likely to become a tax-financed system, through payroll taxes and general revenues. But the average American believes that the Federal Government wastes 48 cents of every tax dollar.

In addition, taxes depress incentives to work and to take business risks. Clinton claims to provide universal coverage, but the cost in terms of jobs, taxes and forgone economic growth may be prohibitive. Cooper provides universal access to people to buy coverage, plus subsidies for the poor. That means that the only people not covered by the Cooper plan are free riders.

While I would like to see more commitment to universality in the Cooper legislation, it is not unreasonable to fix the system first before committing to pour unlimited resources into it, as long as we protect the poor. And if an employer and/or individual mandate may not be politically feasible now, system reform could make it much more feasible in the future.

A mandate could be phased in later or combined with a trigger mechanism such as the one in the Heart bill. The Clinton proposal can be fixed. We hope that the result will be a bipartisan solution that looks a lot like the Cooper bill. Thank you.

[The prepared statement of Mr. Enthoven follows:]



## PREPARED TESTIMONY OF ALAIN C. ENTHOVEN

We can solve the interrelated problems of health care cost and access, while maintaining high quality of care and service, only by fundamental transformation in our financing and delivery system, a transformation that is already well under way.

The traditional fee-for-service, remote third party payment system has failed primarily because the incentives it creates are all wrong: FFS pays more for more, not necessarily better, care. Accountable health plans, which integrate financing and delivery, have an incentive to provide better care at less cost by:

- selecting doctors for quality,
- studying practice variations and adopting cost-effective practices,
- matching numbers and types of doctors to the populations served,
- concentrating costly specialized procedures in efficient regional centers, and
- employing quality management and continuous quality improvement.

The only way to accomplish this is through market forces, i.e., by informed, voluntary decisions of cost conscious buyers who switch to the most efficient system because they see it in their own best interest. Government cannot accomplish this change. Government is rigid and inflexible. According to the Gore Report:

Yet innovation, by its nature, requires deviation. Unfortunately, faced with so many controls, many employees have simply given up. They do everything by the book—whether it makes sense or not. They fill out forms that should never have been created, follow rules that should never have been imposed, and prepare reports that serve no purpose—and are often never even read. In the name of controlling waste, we have created paralyzing inefficiency.

Civil servants are not allowed to use judgement, but in something as complex and subtle as medical care, judgements must be made all the time.

Both the Managed Competition Act of 1993 and the Health Security Act claim to rely on market forces. While there is much in the Clinton plan with which I agree—the provision of universal health insurance, system reform through accountable health plans, and the call for outcomes analysis, quality measurements, and information reporting—the plan does not rely on market forces.

While the Cooper plan empowers people with incentives, information and subsidies where appropriate to purchase health benefits on the basis of value-for-money, Clinton's proposal creates an entitlement that reduces responsibility for people to act to bring about quality cost-effective care.

The Cooper bill limits tax free benefits at the price of the low cost plan in an area. The Clinton plan includes no such limit thereby decreasing the market place reward to a health plan for lowering its price. The Clinton plan leaves market forces weaker than they could be and leaves in place a heavy tax on cost containment.

Cooper limits purchasing cooperatives (HPPCs) to groups of 100. Clinton's Regional Alliances would include everyone. HPPCs are new and largely untested. Cooper would test them first where they are needed most and would leave a large private sector to ensure pluralistic demand. Clinton's plan concentrates massive power in state agencies, easily turned into regulatory bodies or single payers. The Gore Report acknowledges the problems of federal monopolies:

Many federal organizations are also monopolies, with few incentives to innovate or improve. Employees have virtual lifetime tenure, regardless of their performance. Success offers few rewards; failure, few penalties. And customers are captive; they can't walk away from the air traffic control system or the Internal Revenue Service and sign up with a competitor. Worse, most federal monopolies receive their money without any direct input from their customers. Consequently, they try a lot harder to please Congressional appropriations subcommittees than the people they are meant to serve. Taxpayers pay more than they should and get poorer service.

Cooper's National Health Board would have reasonable political insulation through which it would set and update the standard benefits package. Clinton's National Health Board is an arm of the Executive Branch, and its benefits package would be set through the political process where political considerations may mean more than economic and medical merit.

Cooper's proposal makes a limited controllable federal contribution toward subsidies for low income individuals. The Clinton plan subjects the federal budget to a large open ended risk; with a 7.9% cap on employer contributions, the federal budget must pay the excess if health care costs increase faster than wages. Plus, costs of windfalls such as the early retiree contribution and drug and long-term care benefits for Medicare beneficiaries without joining an HMO are difficult to predict.

Weak market forces due to a lack of a tax cap plus this risk to the federal budget force Clinton to set overly ambitious cost containment goals. Even the UK and Canada have not achieved the rates of price increase called for by the Clinton plan. Therefore, Clinton relies on price controls on premiums.

Price controls don't work:

- the incentives are all wrong; health plans are rewarded for fighting regulations, not for innovation and efficiency,
- it is politically untenable for regulators to force health plans to become insolvent, forcing millions to change health plans and doctors, and
- the Fifth Amendment forbids the taking of private property without due process and just compensation including a fair rate of return.

If price controls did work, quality and service would suffer.

As federal revenue requirements grow, the Clinton plan is likely to become tax-financed, through payroll taxes and general revenues. According to the Gore report: "The average American believes we [the federal government] waste 48 cents of every tax dollar." In addition, taxes depress incentives to work and to take business risks. The Clinton plan would drive many people over the 60% marginal tax rate, combining federal and state, income and payroll taxes.

Clinton claims to provide universal coverage, though the cost in jobs, taxes and forgone economic growth may be prohibitive. Cooper provides universal access to people to buy coverage plus subsidies for the poor. The only people not covered by the plan are free riders. While I would like to see more commitment to universality in the Cooper legislation:

- It is not unreasonable to fix the system first, before committing to pour unlimited sums of money into it, as long as we protect the poor.
- If a combined employer/individual mandate is not politically feasible now, system reform could make it much more feasible in the future. A mandate could be phased in later or combined with a trigger mechanism such as the one in the HEART bill.

The Clinton proposal can be fixed. The result, I hope, will be a bipartisan solution similar to the Cooper Bill.

Mr. WAXMAN. Thank you, Ms. Singer.  
Dr. Miller.

### STATEMENT OF DONNA MILLER

Ms. MILLER. I also thank you for the opportunity to be here. I am here today to provide you with evidence that a market-driven, community-based competitive health care reform model, as proposed by Congressmen Cooper and Grandy in their Managed Competition Act is effective and already operational in several communities across this country.

I will describe how the model in Memphis has dramatically changed our health care environment and effectively contained the rising costs of health care. However, Memphis is not alone. You will find managed competition models in other areas and more are developing at a very rapid pace. We are all part of a community movement of business groups that currently represent over 25 million people and are beginning to document very impressive results.

In Memphis, our group represents 55 employers with 145,000 covered lives in the Memphis area and a little under 500,000 nationwide. Through a variety of services and programs such as group purchasing and case management, we have been able to reduce the rising costs of health care and join with the providers to improve quality.

Some examples are the following. The market in Memphis has become extremely competitive, with even the advertisements of the health care industry reflecting the changes. A few years ago ads focused on high technology and "warm fuzzies". Today, ads emphasize high quality and price competitiveness.

Quality has improved through combined efforts of the purchasers and providers identifying and correcting problems. One example is a case of what has happened with our C-section rate. We have had a problem a number of years in Memphis with a much higher than national average, 37 percent of all C-sections, as opposed to 23 percent nationwide. We took this to the quality committee through our managed care network. The physicians aggressively worked on this problem and they were able to drop their rate to 22 percent within 4 months.

The impact of this one effort is dramatic in terms of costs and in terms of quality. A C-section is a major surgical event with much longer recovery time, increased chances of complications and certainly much higher costs.

In our psychiatric and substance abuse managed-care program, we have had the following impact. Admits per thousand have decreased by 59 percent since 1989. Days per thousand have decreased by 80 percent. Average length of stay decreased by 53 percent. Per treatment costs have decreased by 72 percent from an average \$17,320 to \$4,826.

For the past 7 years, using a bidding process through our purchasing alliance, we have group purchased hospital and physician care for our corporate members. Impact on costs, again, have been dramatic.

For over a 5-year period, our companies have experienced an average 6 percent in their average cost per employee increases, as compared to 14.66 nationwide. Actually, if we broke out the end of



1992 from the end of 1991, we found it a little under 2 percent increase in the average cost per employee.

For the end of 1993 analysis, we only have 10 of our members who have been able to give us the data. However, with that data, we have found 0.5 of 1 percent increase. Since I submitted this testimony, we have been able to do weighted evaluations plus add some other companies.

Actually, from what we have got right now, it is showing a 2.3 percent decrease in the average cost per employee. This could change as more data comes in. We have been able now to try to extend this to the small market for fear of cost shifting. Effective immediately, we will be offering a fully insured plan for small employers where they can access the same pricing that we have been able to negotiate for our larger members.

This will convert to dramatically decreased premiums and we will be working through our managed-care network and the selected insurer to expand this into the community.

Health care reform is already occurring. For the first time in decades, we are achieving success in health care cost containment. The Managed Competition Act has the ingredients for promoting similar successes in communities around this country. We urge you to give us the opportunity to continue to do what we are doing and also other communities across the country to do some similar things for this market-based community competitive model. Thank you.

Mr. COOPER [presiding]. We are impressed, Donna. You know, I think I like it better on this side of the panel than on that other side. I may never turn it lose.

I would like to introduce my good friend, Tony Cebun, who is President and Chief Executive Officer of the Tennessee Managed Care Network in Nashville, Tenn.

#### STATEMENT OF ANTHONY J. CEBUN

Mr. CEBUN. Thank you, Mr. Chairman. The Tennessee Managed Care Network is a network model HMO serving about 250,000 members Statewide. The network was developed in a joint funding of the Robert Wood Johnson Foundation, the Commonwealth Fund and Lyndhurst Foundation, by the Tennessee Primary Care Association, an organization initially composed of about 20 section 330-funded community health centers across the State of Tennessee.

Managed Care Network has in excess of 10 years of experience serving Medicaid recipients in Tennessee, first on the voluntary basis to a program that ran prior to the implementation, January 1994 of TennCare, a mandatory managed care program. Additionally, we have been serving the small business and uninsured marketplace in Shelby County, Tenn., which is Memphis, during the past 5 years.

Based on our experience with this market and my 20 years of experience in managed care throughout several regions of the country, I am convinced that the need for national reform is critical. The issue is not whether we need reform, but how we go about it. It was precisely because of this reason that I offer my comments in support of H.R. 3222.

I should make it clear that I am not opposed to the President's plan. However, though we support the spirit and the intent of the President's proposals, his goals and his objectives, and applaud the effort of the First Lady in elevating the Nation's consciousness to the need for health care reform, we find that Congressman Cooper's bill better supports a market-based solution and we think that in the final analysis a market-based solution is ultimately one that has desired effects and fewer of the negative externalities that we fear will be concomitant with a more regulatory driven approach.

We think that the two approaches are similar with the exception that the price controls proposed by the President's plan would not have the needed effect of structural market reform in solving the marketplace problems which have eventuated in having roughly 37 million people uninsured.

Tennessee Managed Care Networks' effort in serving the uninsured was borne out of an idea consistent with our history and a mission of an organization—of our organization, as well as a recognition of a unique market opportunity.

The study on the uninsured performed by the association, with the additional funding support of RWJ and the Hospital Corporation of America and a small grant from the State of Tennessee revealed that the uninsured population may be largely described as young, uneducated, poor, near poor, and more importantly, employed; that 75 percent of Tennessee and about 85 percent nationally of the uninsured represent or are dependents of individuals who work every day.

First, the thing that we have learned in serving that population is that most of the working uninsured, as I said, are employed by small employers with fewer than 10 employees who do not sponsor a group health plan because neither they nor their employers can afford the price of adequate coverage.

In our personal interview survey of small employers, in fact, 67 percent of those surveyed felt that neither they nor their employees would be able to bear the cost for the monthly premium. Faced with the constraints of artificially imposed caps on premium rates and the prospects of adverse selection, health plans struggling to survive may resort to drastic tactics.

They may decrease benefits or they may compromise quality. While the Tennessee Managed Care Network has been committed to serving this population and now continues to do so on an expanded fashion as a result of TennCare, our experience has informed us that we cannot continue to provide innovative, client-oriented services, which has been our hallmark on a long-term and sustained basis if we are forced to operate under a situation of price controls as the President's plan would portend.

Second, while mandatory across-the-board employer sponsorship and participation in a health plan is meritorious, it disregards the negative impact upon those businesses least able to afford this, and that is on small businesses. Clearly, 23 percent of the Nation's work force, according to a 1987 estimate, are working for companies that employ fewer than 25 individuals.

One of the things that happens when this kind of burden is passed on to small businesses is they are forced to attempt to try

to pass this on and they are clearly in a marginal situation, which impacts generally in their bankruptcy.

Third, with the introduction of the Managed Competition Act or H.R. 3222, it enables managed-care plans to compete based on innovative pricing and benefit plan enhancements without the restraints that a premium cap would impose.

As has been evidenced in various commercial markets and now in the public sector with TennCare, the payer is—the payer and consumer is market driven by the value that they can derive from the system. Savage managed-care plans intent on their long-term survival will respond accordingly.

Natural market forces cause competing plans to self-regulate pricing as well as product design. As it becomes increasingly more difficult to distinguish among plans on the basis of price and product, then quality becomes the determining factor of long-term market success.

Let me just conclude my comments here by saying I would caution the assembly to revisit the objectives of health care reform to make quality health care affordable, accessible, and assure that all parties, consumers, providers, insurers, and employers are accountable.

And in the spirit of accountability, I must assert that we would support H.R. 3222, a proposal which enhances market competition without restrictive regulatory barriers.

Thank you.

Mr. WAXMAN. Thank you very much for your testimony.

[The prepared statement of Mr. Cebrun follows:]



PROPONENT TESTIMONY ON HR3222  
"THE MANAGED COMPETITION ACT OF 1993"  
ANTHONY J. CEBRUN, J.D., M.P.H., PRESIDENT/CEO  
TENNESSEE MANAGED CARE NETWORK (NASHVILLE, TN)

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT  
CHAIRMAN HENRY WAXMAN  
WEDNESDAY, FEBRUARY 2, 1994

Mr. Chairman, members of the committee, and members of the panel, my name is Anthony Ceburn and I am President and CEO of Tennessee Managed Care Network, a not-for-profit network model HMO headquartered in Nashville, Tennessee serving over two hundred fifty thousand (250,000) members statewide. The network was developed through the joint funding of the Robert Wood Johnson Foundation, the Commonwealth Fund and the Lyndhurst Foundation by the Tennessee Primary Care Association (nee Tennessee Association of Primary Health Care Centers) an organization initially composed of twenty (20) section 330 funded community health centers. Tennessee Managed Care Network has in excess of ten years of experience serving Tennessee's Medicaid (Aid to Families with Dependent Children) population in a voluntary program prior to the January 1994 implementation of TennCare, a mandatory Medicaid managed care program. Additionally, we have been serving the small business and uninsured market in Shelby County Tennessee during the past five years. Based upon our experience with this market, and my twenty years of managed care experience in several regions of the country, I am convinced that the need for reform is critical. The issue is not whether we need reform, but how we go about it. It is precisely because of this reason that I offer my comments in support of HR3222. I should make it clear that I am not opposed to

the President's plan. However, though we support the spirit and intent of the President's proposal, his goals, and objectives and applaud the effort of the First lady in elevating the nation's consciousness to the need for health care reform, we find that Congressman Cooper's bill better supports a market-based solution. And we think that a market based solution is ultimately one that has the desired effects and fewer of the negative externalities that we fear will be concomitant with a more regulatory driven approach. We think that the two approaches are similar with the exception that the price controls proposed by the President's plan will not have the needed effect of structural market reform in solving the market place problems which have eventuated in having 37 million people uninsured.

Tennessee Managed Care Network's effort in serving the uninsured was borne out of an idea consistent with the history and mission of our organization as well as the recognition of a unique market opportunity, that is serving the uninsured and the underserved. The study on the uninsured performed by the Tennessee Primary Care Association, with the additional funding support from the Robert Wood Johnson Foundation, the Hospital Corporation of America (HCA), and a small grant from the State of Tennessee revealed that the uninsured population may largely be described as:

- \* Young -- children and young adults comprised 54% of the uninsured population;
- \* Uneducated -- 42% of the uninsured were high school dropouts;
- \* Poor or Near Poor -- 72% were economically disadvantaged

yet all income groups are represented (Medicaid only covers 47% of those under 100% of the federal poverty guidelines); and,

- o **Employed** (or dependents thereof) - representing 75% of the population (Nationwide this figure was 85%).

First, what we have learned in serving this population is that most of the working uninsured are employed by small employers (with ten or fewer employees) who do not sponsor a group health plan because neither they nor their employees can afford the price of adequate coverage. In our personal interview survey of small employers, in fact, 67% of those surveyed felt neither they nor their employees would be able to bear the cost for the monthly premium. Anecdotally, one employer stated that "... many employees live paycheck by paycheck. They cannot afford a deduction for something they may or may not use. If they need care, someone will provide it for free or at an affordable cost. If they incur a large hospital bill, they will file bankruptcy and let the courts decide on payment. Bankruptcy is a very common practice here." What plans experience then is adverse selection where high utilizers, those who expect to consume extensive medical and health care resources, will disproportionately select to purchase health insurance while the young and healthy population, burdened with the same economic constraints, will select out of this same purchase option. Faced with the constraints of artificially imposed caps on premium rates and the prospect of adverse selection, health plans struggling to survive may resort to two drastic tactics -- they may decrease benefits or they may compromise quality. While Tennessee



Managed Care Network has been committed to serving this population, and now continues to do so in an expanded fashion due to TennCare participation, our experience has informed us that we can not continue to provide the innovative client oriented service, which has been our hallmark, long-term and sustain a loss such as that which the price controls in the President's plan portends.

Secondly, while the administration's approach of mandatory across the board employer sponsorship and participation in health insurance is meritorious, it disregards the negative impact upon those businesses least able to bear the burden, small businesses. Ultimately, the public will realize this negative impact through: 1) increased unemployment as financially burdened small businesses, representing 23% of the nation's workforce in 1987 (according to the Bureau of Labor Statistics Economic Census, Enterprise Statistics) are forced to close; and, 2) increased prices for goods and services as employee health benefits cost(s) are shifted to consumers. Moreover, although the President's plan has admirably initiated an attempt to minimize the undue burden on the small business by increasing the level of proposed subsidies, the proposed governmental support falls dramatically short of forestalling the deleterious effects. Further, while the President's plan has gone quite a distance in minimizing some of the negative impact upon small businesses, and more specifically minority businesses, it still does abate the disproportionate burden they would experience as marginal businesses susceptible to bankruptcy.

Thirdly, with the introduction of the Managed Competition Act,

Mr. Cooper, and his fifty-six co-sponsors, enables managed care plans to compete based upon innovative pricing and benefit plan enhancements without the restraints of the premium cap imposed by the President's plan. As has been evidenced in various commercial markets, and now in the public sector with TennCare, the payor, and consumer, market is value-driven. Savvy managed care plans with intention for long term survival respond accordingly. Natural market forces cause competing plans to self-regulate pricing and product design. For example, many of the new market entrants for Tennessee's TennCare, formerly Medicaid, market have expanded the government mandated benefit plan with service enhancements which closely mimic those Tennessee Managed Care Network has offered for ten years. As it becomes increasingly more difficult to distinguish among plans on the basis of price and product, then quality becomes the determining factor of long-term market success. Artificial governmentally imposed price controls and mandates do not stimulate value-driven market competition. Instead, the government can better influence the market as a large purchaser of services.

Fourthly, we find that in a marketplace free of burdensome market regulations, increasingly employers (even the smaller ones) will be driven to provide attractive benefit packages for a decreasing pool of skilled employees. This is supported by recent market research which has indicated that in this new healthcare environment, a key criterion in job selection is that of health care benefits. A 1994 EBRI/Gallup study (Employer Benefits Research Institute) found that 18% of employees said that they or

a family member have rejected a job offer, or remained in a job, solely due to health benefits. EBRI also found in a 1993 study, on average employees or their family members, would have to receive \$5,157.00 to be willing to give up their employer provided health benefits (a 7% increase over the 1991 study figure of \$4,835.00). Clearly, employees have a real appreciation for the value of their health insurance coverage and employers competing for a limited skilled work force will structure compensation and benefit packages which are attractive.

In closing, I would like to caution this esteemed assembly to revisit the objectives of healthcare reform -- to make quality healthcare affordable, accessible and ensure that all parties (consumers, providers, insurers, and employers) are accountable. In the spirit of accountability, I must assert that we protect the quality of healthcare through a proposal which enhances market competition without restrictive regulatory barriers.



Mr. WAXMAN. Dr. England.

### STATEMENT OF MARY JANE ENGLAND

Ms. ENGLAND. Good afternoon. It is an honor and a privilege to be able to present before you this afternoon an issue that is very important to all of us, certainly an economic issue, but a personal issue in all of our lives. It is an honor also because I know I your own deep personal commitment to the poor and disenfranchised in this country of which I have great respect.

The Washington Business Group on Health represents—has 200 members, mostly Fortune 500 companies, including our Nation's most knowledgeable, progressive, and successful managers of health care. We are deeply committed to the reform of the health care delivery system, but we wish to maintain an active role for purchasers to provide high quality, affordable health care.

We are particularly supportive of the framework of Representative Cooper and his Managed Competition Act. It would allow us a framework to be able to continue to have purchasers have an active role. Reform started long before this current administration or before issues with Senator Wofford in Pennsylvania. It started with the employer community.

For the last two decades, employers with their money and their workers' productivity have had a major stake in using their market clout to get better quality care at a lower cost. In fact, as you know, Mr. Chairman, at the Washington Business Group on Health, our signature pin is, "It is the delivery system, stupid". And we hope to bring that home, that our employers' success in being able to control costs and increase quality has been through organized systems of care.

This has been developed with a partnership with providers, with physicians and hospitals at the local level to provide a full continuum of care that is affordable and also accountable. We are very concerned that the Clinton health care plan has dropped the word, "accountable" from their health plan.

We also are very concerned that as employers we spend a great deal of time educating our consumers and we—our employees, and we feel that is critical. Why should we exclude employers now as purchasers? They have been able to force providers to give us the kind of data necessary to know whether they are providing high quality services.

We have been able to move forward to fix the delivery system through information that is critical. We particularly support the notion of Representative Cooper in the health plan purchasing co-ops that will address the small market issues for small employers and individuals. That is, these co-ops would not be larger than employers, including employers of less than 100 employees.

It is really important that we all address the issue of preexisting condition and provide services regardless of your disability to a full continuum of care. And we feel that the health purchasing plans will allow small businesses and individuals to have the same kind of market clout that our employers have today.

There are a number of issues that we also feel are important and that is the medical malpractice that needs to be much stronger than in the current Clinton plan as we see it here in the Cooper,

and we would also encourage, as we move to accountable health plans, that we consider holding them liable, with enterprise liability as well. And not just focus on medical malpractice, but look at liability as it relates to those larger accountable health plans.

We support the notion of including Medicare as part of reform, particularly of incentivizing our old folks to be part of accountable health plans by giving them a drug benefit. We also support the revamping of Medicaid, and the insurance, however, that the poor get subsidies so that a mother with a handicapped child can continue to work and get the full benefits that she can get now under the Medicaid program.

We also feel it is important to have a comprehensive continuum of care. We know that accountable health plans with the right kinds of incentive, organized systems of care, can provide a full continuum, and it is important that we recognize the commitment that Representative Cooper has to a full continuum of care for the mentally ill, for mental health and substance abuse.

Building on the examples of Federal Express and Digital. Federal Express, as you know, has had remarkable success by providing a full continuum of care for the mentally ill and substance abusing employees, and have been able to save \$18 million over the last 3 years and improve the number of patients getting care, as well as the quality of care for their employees. So I commend Congressman Cooper for his leadership in applying managed competition to mental as well as physical health care and for supporting the systematic change in service delivery that have enabled large purchasers to eliminate limits on mental health coverage.

This concludes my prepared statement. I appreciate the opportunity to appear before the committee and hope that you see in your wisdom to allow the employers to continue to be active purchasers because they will improve the quality of health care for their employees and all Americans. Thank you.

[The prepared statement of Ms. England follows:]

## STATEMENT OF

### THE WASHINGTON BUSINESS GROUP ON HEALTH

Good morning. It is always an honor to speak with you. But it is an extraordinary privilege to be here today because your Committee is considering one of the most important reforms in our nation's history. Health care is not just the largest economic sector in our country, and one of the largest economies in the world. It is also one of the most profound personal issues in all of our lives, with the quality and availability of health care as critical issues.

#### **The Washington Business Group on Health**

As you know, the Washington Business Group on Health (WBGH) is the nation's only organization representing large employers solely on issues related to health care. It was created 20 years ago to address the growing imbalance between the rising prices that employers were paying for health care, and their lack of control over what they were buying.

Today, WBGH's 200 members, mostly Fortune 500 companies, include the nation's most knowledgeable, progressive and successful managers of the health care they provide for their more than 30 million employees. We often describe the Business Group as representing the evolution of large employers from passive payers to active purchasers of health care. I would like today to share the most important lessons we have learned in that evolution.

Our membership spans the gamut of big business in America. In fact, at Chairman Rostenkowski's December 15th hearing on the effects of health care reform on the national economy and jobs, two of our member companies -- Ford Motor and PepsiCo -- testified on the same panel, but highlighted the diversity in the business community's reactions to the Clinton plan.

This diversity is a source of strength for WBGH. It means that our member companies suppress their differences to concentrate on the goals that we share. Reforming the health care delivery system, and maintaining an active role for employers in health care purchasing, are two of the most important common goals. Achieving these goals will ensure vigorous competition among high quality, affordable health plans. Congressman Cooper's proposed Managed Competition Act would provide a framework to do that.

#### **Organized Systems of Care**

The members of WBGH have been involved in public and private sector efforts to improve health care delivery, and have been advocating system-wide health reform, for two decades. I say this not just to brag, but to remind the Members of this Committee that health reform did not begin with the Clinton Administration, or the presidential campaign, or even with Senator Harris Wofford's campaign in Pennsylvania. Health reform began, and is going on now at an accelerating pace, within the business community.

Health reform began because employers with *their* money and *their* workers' productivity at stake started using *their* market clout to get better quality health care at a lower cost.



What employers discovered is that they could not solve the discrete problems in health care -- the uncontrollable costs, the variable and often unknowable quality, and the unequal access -- until and unless they fixed the way that health care services are delivered. This is why WBGH's signature button reads: *It's the delivery system, stupid.*

The secret to our employers' success is what we call *organized systems of care* or OSCs.

Our use of the term OSC is comparable to what we understood the White House to mean by their early use of the term "accountable health plans." (Unfortunately, the word "accountable" seems to have been dropped along the way.) The concept means that unified and accountable health care delivery systems serve all Americans and replace the fragmented, inefficient, costly and unmanaged fee-for-service approach that many health consumers still face today.

Organized systems of care integrate financial risk with responsibility for outcome. These OSCs provide a full continuum of care, and are accountable to patients and purchasers for their cost and quality.

Largely because of the pressures exerted by large employers as caring, invested and informed group purchasers, providers are organizing into systems that can deliver the highest quality care at the best price. In OSCs, services are integrated and care is managed for optimal outcome. Waste and redundancy are reduced because procedures are performed not for their profit but for their efficacy. Consumers are educated about their role in their own health, and empowered to take control over the quality of their lives. Iatrogenic or physician-induced problems are drastically reduced. In fact, the entire focus of care shifts from sickness to health.

## The Quality Of Care

To purchase good care, large employers understood that they had to have good information. The Committee should appreciate that when employers first started asking the questions that would allow them to evaluate, monitor and improve the quality of health care, there were no answers. In the beginning, not even the best organized health systems could tell purchasers what their Cesarean-section rates were (let alone the rates of vaginal births after C-sections), or the hospitalization rates for treating asthma, or the relapse rates after treatment for substance abuse.

To meet the need for this information, employers began an effort that resulted in the recent publication of *HEDIS.2* (the Health Plan Employer Data and Information Set). As explained in the document, *HEDIS.2* helps purchasers to measure the value of the services they are buying and to implement programs that assure continuous quality improvement.

Throughout this process, one of the most exciting discoveries was that when purchasers concentrate on improving *quality*, the cost of care comes down. Actually, this won't surprise any Members of the Committee who have availed themselves of the highest quality care in this country, which often comes at the most reasonable prices, from centers of excellence such as the Mayo Clinic.

There are several reasons for the often inverse relationship between cost and quality. In medicine, as in other professions, skill develops over time and with experience. It is not surprising that a physician who has performed hundreds of coronary bypass procedures is better at it than is a beginner. Expertise also develops with the increasing experience of surgery support teams and other ancillary personnel. In addition, high volume reduces per capita cost. Finally, the symptoms treated by high-tech, high-cost procedures are often caused by mental and emotional problems. These symptoms often disappear with appropriate, low-cost mental health care.

### **The Role Of Employers**

Given all that employers have learned, and all that they have accomplished, it would be a terrible irony if reform excluded them from the purchase and delivery of health care. Unfortunately, the Clinton proposal offers no recognition of health care as an employee benefit issue. Instead, it seems to perceive employers as merely the payers for care.

Under the current Clinton proposal, the costs and other burdens of creating a corporate alliance are too high, and the returns for those who do are too low. We have found relatively few corporations, even among those large enough to do so, that would create their own corporate alliance.

Setting the threshold at 5,000 employees for even the opportunity to choose not to be in the regional alliance defies the concept of "managed competition." It would leave only 18 percent of the population eligible for corporate alliances. The Washington Business Group on Health has long endorsed a threshold of 100. In fact, when then candidate Bill Clinton first used the term "managed competition" during the summer of 1992, there were only two working versions of it. The original was the concept developed by the Jackson Hole Group. It relied on a threshold of 100 for what they then called "health insurance purchasing cooperatives." The only other version was Representative Jim Cooper's Managed Competition Act of 1992. In the Act as introduced in the 102nd Congress, the alliance threshold was 1,000. In the most current version it is 100, with the option for states to raise it (to approximately 500), as long as the alliance does not include more than 50 percent of the employees in the relevant area.

If we really want to give competition a chance to produce better health care -- as Representative Cooper says, perhaps its last chance -- the threshold for mandatory participation in the regional alliances must come down. Toward this end, we were delighted to hear Treasury Secretary Bentsen say last week that the Administration is flexible on this point.

We must emphasize that simply charging employers a percentage of their payrolls to finance health care coverage sold to individuals in large regional alliances would not keep these employers engaged in improving the quality and reducing the cost of care. Giving them seats on the boards of directors of these alliances is simply not a substitute. We very much want the continued active involvement of these skilled, experienced and successful evaluators, negotiators and purchasers of care. This should be a central goal of health care reform.

The role that employers as purchasers now play cannot be supplanted by the bureaucracy detailed in the Administration's proposal. The very size and cost of this bureaucracy is incongruous with Vice President Gore's proposal to downsize government. Throwing the 41 percent of persons who work for small (1-99), medium (100-999) and large-but-not-really-large (1,000-4,999) businesses into these public pools would destroy much of the good that has been accomplished, and waste the value that employers as purchasers add to the system. It would also eliminate many of the most successful purchasing coalitions, such as the Memphis Business Group on Health. Instead, all of these people, and all of those in the largest (5,000+) companies that did not form corporate alliances, would be evaluating, negotiating and purchasing their plans as *individuals*. With none of their own money at stake, and no investment in worker productivity, the alliances could never do what employers now do. This opinion is shared by many businesses and individuals throughout the country.

### What We Need

We need health care reform. But we must take this opportunity to do it right. And if doing it right requires more time than the current politically driven time tables would allow, then we should take the time that it requires. It would be a terrible failure if, in the rush to pass some kind of reform, we simply rearranged the financing for the current system, and did not fix the delivery system.

Toward this end, the Washington Business Group on Health respectfully makes several specific suggestions.

**Small Market And Delivery System Reform:** For individuals and small groups, the business of insurance has become "risk avoidance." Small groups with even one high risk person are being hit with huge rate increases or are asked to exclude those employees from health coverage who need it most. This has created a situation where the sickest people often have the worst access to care.

For this reason, the Washington Business Group on Health endorses reforms that would redesign the purchaser market to pool individuals and private and public small employers into coalitions that are large enough to insure access to coverage and achieve economies of scale. We recommend that these purchasing pools include persons who buy coverage as individuals or single families, and those who work for businesses with 100 or



fewer employees. These coalitions would serve to organize very small groups into pools large enough to force increased competition among health plans.

The individuals who purchase in these pools must have access to organized systems of care or accountable health plans. Such plans should offer comprehensive, federally-defined coverage. These plans should be prohibited from denying, or prohibitively pricing, coverage for selected individuals or for preexisting conditions. They must report and make available the full range of information that is necessary for consumers to be wise purchasers. In effect, the health plans will be forced to compete on the cost and quality of care, rather than on benefit design and risk avoidance.

**Preservation of ERISA Preemption:** Multistate employers must be able to preserve and continue their successes in health reform. We cannot return to the "bad old days," when large employers who wanted to provide health care coverage for their workers had to contend with 50 different sets of rules and 50 different benefit plans. If each state is allowed to impose its own system on employers who have workers in every jurisdiction, then those employers will simply stop providing coverage.

**Antitrust Reform:** WBGH endorses reform of antitrust law to protect and encourage the development of vertically integrated health networks. Our vision of organized systems of care encompasses the close cooperation of a broad range of providers, the provision of comprehensive services, the availability of all information useful to the consumer, and administrative ease. The vertical integration of many different facilities and providers is crucial to achieve this ambitious vision.

WBGH also supports the redesign and enforcement of antitrust law to ensure competitiveness in the health care marketplace. This may require repeal of the McCarran-Ferguson Act, the 1945 law through which the federal government ceded control over the insurance industry to the states, including an effective exemption for the industry from federal antitrust law. Bringing insurance companies under fair competition laws would bar anticompetitive insurance practices while furthering the goal of health system reform: the efficient delivery of affordable, accessible, high-quality health care.

**Enterprise Medical Liability:** WBGH strongly believes that the current medical liability system is in need of fundamental reform. The current system: 1) does not effectively deter negligent medical care; 2) reduces access to needed services while increasing utilization of costly, inappropriate care that can actually threaten a patient's health; and 3) resolves claims in an inefficient and inequitable manner.

WBGH supports the inclusion of enterprise liability in overall tort reform to improve the medical liability system in the context of organized systems of care. Other elements of tort reform should include caps on noneconomic damage awards, the use of alternative dispute resolution mechanisms, and the increased use of practice parameters. Together, these measures would provide greater incentive for the OSC or accountable health plan to monitor

and improve the quality of care, would lead to a more efficient and equitable compensation system for injuries due to malpractice, and would decrease the incidence of negligent care.

**Inclusion of Medicare:** WBGH strongly believes that health care reform should benefit *all* people. Older Americans, who are higher utilizers, are particularly vulnerable to the worst aspects of fee-for-service care, including its high cost, low efficiency, shortage of good information, lack of coordination and absence of management. Unsurprisingly, older Americans suffer the most from the results of unmanaged care. An estimated 25 percent of hip replacements are in persons in this population who have fallen because they were overmedicated.

WBGH strongly recommends that health reform be structured to extend the benefits of organized systems of care to those who could benefit most from them, including Medicare and Medicaid beneficiaries. Studies of Medicare beneficiaries who voluntarily joined HMOs have shown that overall, consumer satisfaction is high. In a recent study done by Mathematica Policy Research, Inc., 93 percent of Medicare HMO enrollees reported that they would recommend their HMO to a friend or relative.

We think it is particularly ill conceived to add a prescription drug benefit to Medicare while specifically excluding the program from reform, as the Clinton proposal does. Coverage of prescription drugs has been one of the major inducements to bringing older Americans into managed care, and this approach would take away this incentive.

Furthermore, WBGH endorses a subsidy for the poor up to 200 percent of poverty, and the elimination of Medicaid. This would allow people to work and be assured of health care services for themselves and their children.

**Support for Information Technology:** "High technology" often gets criticized as a cost driver in health care. And, in fact, the most complicated, invasive and expensive treatment is often *not* the best care. Unfortunately, however, the use of *information* technology is in its infancy in health care.

Good health care, including integrated medical records and reliable determinations of cost, quality and outcomes, requires the use of information technology. Numerous demonstrations bear witness to the utility of information technology for: measuring health plan performance; assisting patients in making informed decisions about care options; coordinating care across treatment sites; and enhancing service delivery in rural and urban underserved areas. However, there are few incentives to integrate information technology into health care delivery. Consumers, group purchasers and policymakers are generally unaware of the contributions to access, cost and quality that information technology could make, and they have been slow to advocate its development and use.

Health care reform provides an excellent opportunity to integrate information technology into emerging health care delivery systems. WBGH hopes that whatever reform is enacted will address the current barriers to optimal use of information technology,

including provider reluctance, the lack of technology standards and the absence of reimbursement mechanisms.

**Comprehensive Continuum of Care:** WBGH members have learned that to be high quality and low cost, health care must be comprehensive. WBGH supports comprehensive coverage defined by a National Health Board as we move toward providing treatment based on determinations of medical necessity, efficacy, severity of illness, and level of functioning. Those individuals who need intensive care should be able to get it, while the movement of individuals to less intensive levels of care should be encouraged. OSCs or accountable health plans must offer a full continuum of services, including preventive, primary, acute, rehabilitative and chronic care.

As a nation, the only way we will be able to afford comprehensive health care for everyone is to encourage prevention and early intervention. More than half of the illness resulting in early death and disability can be prevented or effectively managed. We can encourage preventive practice through educational efforts, financial incentives to seek early treatment, and good communication between primary and specialty care providers. This can best be done in a system consistent with managed competition where health plans are held accountable for the cost *and* outcomes of care.

On the issue of coverage for mental health and substance abuse care, I testified before this Committee on December 8th to emphasize that the best possible public policy is to provide for this category of disease as we do for all other medical illness. If we are to achieve affordable, quality health care, we must reform our health care system so that all health problems are effectively treated. Mental health and substance abuse problems cannot be an exception. They are prevalent in every aspect of our society, including our workforce.

Experience in private sector health plans demonstrates that limiting the benefit for mental health and substance abuse services undermines cost containment and quality improvement. By managing care with a systems approach, employers such as Federal Express, Honeywell, and Digital Equipment have been able to increase access to care, improve employee satisfaction with the health plan, hold recidivism rates steady, and drastically reduce the cost trend for mental health care. In many cases, the cost trend for mental health is well below that for medical and surgical care.

Federal Express exemplifies much that we have learned about organized systems of care. With a managed approach, including removing the barriers to outpatient services and including a full continuum of care, Federal Express saved more than \$18 million in the first three years of their managed mental health program. Employee satisfaction rose from 85 percent at the onset of the program to its current level of 91 percent. In addition, recidivism has remained constant since the plan was implemented.

I commend Congressman Cooper for his leadership in applying managed competition to mental as well as physical health care, and for supporting the systemic changes in service delivery that have enabled large purchasers to eliminate limits on mental health coverage.

Eliminating limits on mental health care that do not apply to physical health care encourages treatment based on medical necessity and appropriateness. It corrects some of the inefficiencies in service delivery driven by benefit design, and promotes the incorporation of the best available care.

Mr. Chairman, this concludes my prepared statement. Again, I appreciate the opportunity to appear before the Committee and would be pleased to answer any questions that you or other Members of the Committee may have.



Mr. WAXMAN. Thank you very much for your testimony. I want to commend each of you for your presentation to us. I think it was very worthwhile.

Let me ask Ms. Miller, Mr. Atwater or Dr. England, since you are representing employers, this bill doesn't end the cost shifting that is rampant in our current system. The only effective way, I believe, to end cost shifting is to assure that everyone is covered. And I think we have established that the Cooper bill doesn't cover everybody, so that, therefore, those who aren't covered are going to have their care, probably the most expensive emergency room and the cost will be shifted to those who are insured.

Under this bill, employers who decide to contribute to the health coverage of their employees will continue to bear these health care costs of workers and their families that don't provide coverage because of that shift. As business people, how do you intend to protect your firms against that kind of cost-shifting under this bill? And if you can successfully avoid having cost shifted to your firms, what do you think will happen to Medicare beneficiaries and the providers that serve them?

Mr. Atwater, do you want to respond to that, or Doctor England?

Mr. ATWATER. Well, we strongly believe in universal access to health care, and all the studies we have seen of the Cooper plan would indicate that enactment of that plan would cover more than 80 percent of those that are currently uncovered, so that the remaining people whose costs might be shifted are exactly the ones that were discussed in the first panel. They would tend to be young, healthy adults, who put a very small strain on the system. So that the cost shifting that is left with those few people would be very small indeed.

The major cost shifter in today's health care system is, in fact, Medicare and Medicaid, which pick up only about 80 percent of their costs. And under the Clinton administration bill, when they are—when the Medicaid people are moved directly into the system, that cost shifting would continue to go on. So I think the Cooper basically deals with that issue.

Mr. WAXMAN. OK. Any other responses, Ms. Miller?

Mr. MILLER. I would like to add one thing to what he said on that. I agree with what he said, that through—given the small group purchasing power to the alliances, they will be able to expand the employer-based coverage much more because the market will be able to offer a more competitive price. And again, through the market itself it will change and it will only leave the cost shift, again, from the Medicaid population, the Medicare. I agree—

Mr. WAXMAN. Well, there is a cost shift for Medicare, but the Cooper bill would cut Medicare by \$40 billion. Clinton, of course, cuts Medicare as well. But, Dr. England, you have a cost shift from Medicare. You have a cost shift from the uninsured who continue to be uninsured, and that is going to be shifted on to employers. How do you respond to that concern?

Ms. ENGLAND. The Medicare issue, we feel that all the public programs should be incorporated into reform and not allowed to remain outside. If this reform is good for us that are working, then it should be good for all Americans. And when we talk about the Medicare cost increases, you are talking about trend. We feel that

if Medicare patients were included in accountable health plans and with the incentive of the additional drug benefit, you would actually be able to reduce costs.

One of the problems we have now is that old folks don't pay for their medications, and as you know, then get into serious trouble and arrive at the hospital door because they haven't taken their diuretics or their medication. So we would encourage that if people were allowed to have a full Medicare benefit within the accountable health plans, that would actually reduce costs. And what the Representative Cooper—

Mr. WAXMAN. Excuse me, I just want to interrupt you. I just understand, would you do away with Medicare and have them as a part of the whole system?

Ms. ENGLAND. Yes, yes, I would.

Mr. WAXMAN. So everybody in the same system. So do you envision the system is going to try for prescription drugs?

Ms. ENGLAND. Yes, I do, full coverage of prescription drugs. If you are going in this modern type of medicine—

Mr. WAXMAN. Do you know whether it is the case? You think it ought to be, but that benefit package is going to be decided by some group.

Ms. ENGLAND. It is going to be decided by what is effective, and there is no way today with modern medicine that you can provide care without having full access to prescription drugs.

As we all know, as we get older and older, we need more drugs to keep the system moving along.

Mr. WAXMAN. I am an old Democrat, I know exactly what you are saying. Now, so you would—would you recommend that we change the Cooper bill to have the Medicare program brought into this? Did the rest of you agree with that? Ms. Singer, your—you are representing Mr. Enthoven. As I understood the Jackson Hole Enthoven theory, the cost burden was supposed to be borne by the individual by eliminating that tax break that rewards these higher priced plans. Isn't that correct? Speak into the mike.

Ms. SINGER. You are referring to the limit on tax free benefits?

Mr. WAXMAN. Yes.

Ms. SINGER. The marginal differences in the costs of the plans would be borne by the individuals or the employers if they were—if they opted to pay for that.

Mr. WAXMAN. But under the Enthoven theory, that would not—that would then be considered as income and not—and, therefore, taxable to the employee; isn't that correct?

Ms. SINGER. It would be taxable to the employer if the employer paid for it. Or it would be—it would be taxable to the employee if the employee paid for it.

Mr. WAXMAN. As I recall the Enthoven theories, as I read them some time ago, he wanted whoever pays for it, the employee, to have it counted as income. If employers paid for it, there wouldn't be that exclusion from income that is now in the law, so that people would understand that they have to be conscious about price because they are going to be in effect paying for a higher priced health care plan if they want it. And if they want it they can buy it, but they have to be able to pay for it and understand that they

are paying for it and not some amorphous corporation employer somewhere else. Isn't that right?

Ms. SINGER. Yes. The idea is that the individual is fully cost conscious of the differences and the price.

Mr. WAXMAN. What would you think of the Cooper bill if the tax change were eliminated and there was no change in taxes from what we now have?

Ms. SINGER. I think you would have much weaker market forces. You know, the tax free benefits right now subsidizes the more expensive plans. So you would continue to do that. You would cut by a margin people's incentives to choose more efficient plans and you would cut by that same margin the incentive for the health plans to lower their costs.

Mr. WAXMAN. One of the goals of reform is not only to cover people that aren't covered, but to figure out some way to hold down the tremendously increasing costs that we are seeing in health care, except for that period of time when Congress is looking at reforms. That seems to produce some drops. But what—how do we achieve cost controls under the Cooper proposal? Is it only because we provide the purchasing groups and the changes of the taxes so consumers feel the cost to them? Mr. Atwater.

Mr. ATWATER. Well, there are really three systems that can control costs. The first is the individual that Ms. Singer was talking about. And it is under the Cooper plan the individual is very much in the act. As I mentioned in my testimony, we give large incentives, up to a 50 percent saving on your premium, to incense people to pay attention to their health care.

And as I mentioned in my testimony, our health care costs are going down. The second group that works on this is corporations. And they, under the Cooper plan, as today, also have incentives, as we do and as I mentioned in my testimony.

The third group, of course, is the way the health alliances perform their purchasing. That is the only area in which there is any incentive under the Clinton plan, and since there will probably be only one major health alliance in any given State, I think most people think 90, 95 percent of the employees will be in the regional health alliance. There will be essentially no market disciplines in that plan whatsoever.

The Cooper plan preserves all three of the market disciplines.

Mr. WAXMAN. Thank you very much.

Mr. Cooper.

Mr. COOPER. Thank the chairman for yielding and I would like to thank each one of the panelists for the personal sacrifice they made being here today. And believe you me, I wish you could have gotten on earlier.

The first question I would like to direct to Mr. Atwater. It is my understanding that you are a member of the business roundtable. They have a meeting this evening to decide whether to endorse or to delay an endorsement or to oppose the Cooper bill. Have you ever seen a business roundtable vote receive so much publicity as this one?

Mr. ATWATER. I don't think there is any subject that is much more important than health care reform, and the meeting is not this evening, it is in about 7 minutes. But, no, I have never seen



as much public interest, nor as much individual lobbying of CEO's as has gone on this time.

I think it is unprecedented in any business organization, not just the business roundtable.

Mr. COOPER. Would you feel free to describe for us some of the lobbying that has gone on prior to this vote?

Mr. ATWATER. Well, I think everyone is aware of what has gone on. There has been calls from everyone from congressional chairmen to members of the administration, suggesting that we not support your plan.

Mr. COOPER. Did they give reasons for doing that or did they—I don't want to make you late for your meeting and you have been extraordinarily generous to spend this much time with us, but I appreciate your leadership on these issues, not only with your own employees, as well as in the State of Minnesota.

It is my understanding that Minnesota health care costs are about 18 percent below the national average and health outcomes are better. They are proof positive that more efficient care works for people.

Mr. ATWATER. Markets work, and I think our experience indicates it. If I could take 1 more minute, I would like to comment on the tax deductibility issue that was so heavily discussed in the previous panel.

When there is a common set of health parameters, then everybody is going to be bidding against those. And I believe the low cost program of any quality is also going to be the common market price, as it is in almost any commodity-type business. When the—when the product is established with product specifications, virtually everybody comes to a common price. So most corporations are not going to find that their particular plan is way above the average because the average and the low cost are going to be very, very close to each other.

And I think it is an important fact, Mr. Chairman, that did not come out in the original testimony.

Mr. COOPER. I appreciate that. Dr. England, the Federal Express experience providing flexible mental health benefits, is that experience transferable to other corporations?

Ms. ENGLAND. I think it is transferable and has been transferable. I think the important lesson we can learn from instead of having a limited benefit, but of allowing the health plan to make the determination of what is necessary and appropriate for mental health and substance abuse and being able to control costs, is what can be done for any health benefits.

And that is why we like the idea of the National Health Board setting up a benefit structure of what is effective and what gives good outcomes. And that can be true across the board, not just in mental and substance abuse, but across the board in medicine and surgery, which is particularly acute in the mental and substance abuse area, because for so long we have had a limited benefit.

So, yes, it is, and many of the companies represented here in the room, and as you know, my board is here in the room, and many of them have experienced the same kind of cost controls. And the important issue, I think, in the mental health area is that we have actually been able to increase the number of people getting serv-

ices. And like in Federal Express where only 2 to 3 percent got coverage under the original plan, when they moved to this comprehensive flexible plan, they were up to 8 or 9 percent of their employees were able to get access to services early.

Mr. COOPER. Thank you. I hope that your board has extra sympathy for those of us who work in and with Congress as a result of today's hearing.

The next question is for Dr. Miller. The following panel will have a witness from the Service Employees International Union. It is my understanding that he will suggest that purchasing groups such as yours in Memphis have not been effective in controlling costs or encouraging firms which don't offer coverage to do so.

What would your response be?

Mr. MILLER. He needs to come to Memphis and visit with me and I will give him some information to show that we have been very effective. Indeed, I have been able to expand this, to offer it to the smaller employer market, which is, of course, the gravest concern that we had, was that big business would cost shift over to the smaller employers.

They now can access the same pricing as the big employers, which means that a company of 25 employees who is insured will have the same pricing by the hospitals and the networks that the Federal Express' employees do.

A second thing is that what we have found and documented in Memphis is improved quality and efficiency. And when you find improved quality and efficiency in the delivery of care, they are not delivering that improved quality just to the members of my group. That improved delivery is being delivered community-wide.

Mr. COOPER. You are part of a national coalition, as I understand it, of alliances like, or purchasing groups like yours all over the country. Do you recall exactly how many cities are involved in that group and whether those are just large cities or whether there are smaller communities as well?

Mr. MILLER. I think we currently have about 125 business coalitions that belong to the national business group, probably 300 business groups nationwide. Of those groups, maybe currently a very small percentage are doing the purchasing alliances. We have got groups in Florida, I think Minneapolis, Denver, but it is growing.

Every day we have more and more of the business groups that are developing these alliances, because it is working. You know, if you have 6 percent average increase for 5 years compared to 14.66 percent in other parts of the world, and then we actually are now experiencing decreases, then it really shows that there is something there that is working for not just the business group members, but I think for the community as a whole.

Mr. COOPER. Thank you. The next question is for Mr. Cebun. There is considerable skepticism on this panel whether managed care works, period, much less for poor people. Do you think it does?

Mr. CEBUN. Well, I have been in managed care for over 20 years. A large portion of that time has been spent serving the Medicaid population. From my experience in both the private sector plans that I have worked with, I started, as well as those involving public sector, managed care does work. It does—whether managed care saves money is yet to be seen in terms of savings, because I

believe that whatever savings are achieved, that they have to be plowed back, if you will, or invested in the population served, in the form of additional kinds of benefits as what we have done with the Medicaid population.

I think in the short term, there is no doubt in a marketplace where there is so much waste that managed care can help to contain the cost of providing similar benefits there. There is no doubt about that. That is almost unequivocal.

Mr. COOPER. How about in meeting basic human needs? I think we realize there is excessive testing sometimes today. If we move to a managed-care environment, is there too little testing? Are human beings left out?

Mr. CEBRUN. No, I don't think so. In the plan that has the right set of incentives, I think there are already some built in, and if the regulations don't go too far, I think the incentives are to keep people well. So invariably what happens is that the plan, rather than sitting back and waiting for individuals to become ill or to continue to engage in behavior or to expose themselves to certain kinds of risk, the plan attempts to move aggressively to help to see if it can better educate that consumer to avoid certain risks to change their behavior.

The resulting impact is a tremendous amount of dollars that are not spent on acute care are then available for even more health education and more testing; that is, tests for those individuals that we find at the highest risk. You can take some of the dollars and really begin to address some of the individuals who are at the highest risk and maybe have the highest level of unmet need. That may not necessarily manifest itself in the benefit plan that is available.

Mr. COOPER. Last question for Ms. Singer. As you know, and I appreciate your fine work on this issue as I appreciated the chance to work with Mr. Enthoven. Can you think of an alternative to the employer mandate that would persuade people on this panel that we could achieve universal coverage?

Ms. SINGER. Yes, we have been doing a lot of thinking about it, because we see pros and cons of both an employer and an individual mandate. We think that although employer mandate distributes the burden across all the employers, there is a possibility of unemployment effects and you do end up shifting cost to employers. And if you are trying to create an explicit financing mechanism, that is not the way to do it.

There is also the possibility of an employer mandate being inefficient unless you can find a way to effectively target the subsidies to individuals within firms. So the—an alternative is an individual mandate which would be more expensive because you wouldn't be shifting burden on to employers, but at least it would be explicitly financed.

One other notion that we are examining and we are beginning to favor is something that we are calling a free rider tax, which is mostly an enforcement mechanism. But as I said, under the Cooper proposal, the people that are left uninsured are principally going to be free riders. So if you create a free rider tax, you can target your enforcement efforts in such a way that you are focusing on the people who should be able to afford insurance, but don't go out and get it.



As opposed to necessarily targeting—you could have less strict enforcement measures for those people who are low income who you are offering subsidies to, but for whom those subsidies might not be sufficient even with what we provide.

Mr. COOPER. It would be kind of like a mandate, but only for the willfully uninsured. That is interesting. If I could just ask the chairman's permission to submit for the record one more document.

Mr. WAXMAN. Without objection, we will be pleased to receive the document for the record.

Mr. COOPER. Thank you.

Mr. WAXMAN. We have got to move on, but I can't help but try to get a clarification. The free riders that you would tax, are those the employers that don't provide insurance to their employees or the people who don't buy insurance for themselves?

Ms. SINGER. The way we have been thinking about it is you would be taxing the individuals who aren't purchasing the insurance for themselves.

Mr. WAXMAN. What do you do with an individual who is making over—just barely over 200 percent of poverty and they can't afford to buy insurance? You are going to tax them in addition?

Ms. SINGER. No, see, that is what I said, the sort of good thing about a free rider tax is you could target the enforcement so that you were strictly enforcing it on people with high incomes, and less strictly enforcing it on people with low incomes. The problem with the subsidies, I mean even though—subsidizing people out to 200 percent, you may argue about whether or not that is sufficient.

What we do know is that subsidies are expensive. So you have an option between providing greater subsidies and spending more money from the Federal Government. So there is this trade-off. We do know that whatever—you know, we do know that right now in the Medicaid program, what you have is, you know, a cliff at whatever percentage of the poverty level you are providing those benefits for. And under the Cooper proposal, these phasing out of subsidies are at least going to improve upon that.

Mr. WAXMAN. But you still have the cliff. It is a little higher up, but it is a cliff nevertheless, and it is even a cliff for those under 200 percent of poverty if the subsidy is not enough for them to make up the difference. But once you are over the 200 percent of poverty, you have got no subsidy at all. You have got to come up with the money.

There are some figures I saw that showed that it might be 17 percent of their income if you measure the cost of the premium at what the Clinton benefit would be evaluated. So for those people, they may not be able to afford it. You are right, we could raise the subsidies and cost more money. What do you recommend we do with those people? They want insurance, they just can't afford it. Their employers—and they are working people and their employers won't provide it to them because they choose not to.

What do you do to those people?

Ms. SINGER. Well, what we are considering now is the opportunity for a commission that would be part of the National Health Board would reassess the needs. And if, you know, you can look at the percentage of people given those subsidies that are buying and

not buying to determine whether or not it has a reasonable subsidy to be providing.

And if you determine that it is not a reasonable subsidy, you would make a recommendation to create greater—to increase the subsidies to the people that you are providing to, and increase the numbers of people that you are providing subsidies to. But as I said, again, you know, you have to make that trade-off with how much you want to spend.

Mr. WAXMAN. Do you think employers might find it an incentive to drop coverage if they find that there is a subsidy for their employees who are at fairly low income?

Ms. SINGER. They may. We think that the—given the sort of competitive nature of the labor markets, most employers who are currently providing insurance would sort of have to continue to do that. But there may be some of that effect, which is, you know, which is one of the pros for an employer mandate.

Mr. WAXMAN. Well, when you think of 39 million people without coverage and they are not the poorest of the poor, because they are already covered by Medicaid, and two-thirds of them, presumably, are working people or their dependents. You have got a lot of employers, most likely small businesses, that aren't covering their employees now.

And, you know, I guess it would be more affordable, presumably, under this system and you try to make the market work more efficiently. But I guess we would have to look at it very carefully. Is that what you are suggesting?

Ms. SINGER. Yes.

Mr. WAXMAN. Well, I thank you very much. You have been very helpful. I had a question of Dr. England, which I won't ask because we have not even finished the morning session.

Ms. ENGLAND. Perhaps I could come and visit with you.

Mr. WAXMAN. Well, I was interested in an esoteric question of how you think mental health would be handled, because I know you are a psychiatrist. And a lot of psychologists and social workers tell me they fear that these managed systems will exclude them because the medical people will favor psychiatrists. And I don't think you would want that to happen, because—

Ms. ENGLAND. That has not been the experience in most of the organized systems of care that our employers use. It usually is a combination of psychologists, social workers and psychiatrists. As you know, in the public sector—

Mr. WAXMAN. One would think so.

Ms. ENGLAND. And in the public sector under the Medicaid program, we have a multidisciplinary approach, and that is our approach, that it should be multidisciplinary.

Mr. WAXMAN. We won't have time to get into that issue. Come and visit me. Thank you very much. You have been terrific. I appreciate your testimony. It has been very helpful to help us understand the legislation.

Now, to move on to further this morning's schedule of witnesses, we have a panel that is here to testify in opposition to H.R. 3222. They do so from different perspectives, those of employers, workers, providers and consumers. Curtis H. Barnett is Chairman of the Board and Chief Executive Officer, Bethlehem Steel Corporation,

and is testifying today on behalf of the National Leadership Coalition for Health Care Reform.

Anne Bryant is Executive Director of the American Association of University Women. She is testifying on behalf of that organization and the Campaign for Women's Health. John Howley is Assistant Director of Public Policy at the Service Employees International Union of Washington, D.C. Mr. William Coleman is President of the American Academy of Family Physicians, and Ronald F. Pollack is Executive Director of Families USA Foundation in Washington, D.C.

I want to welcome you all and I express my apologies to you because I know some of you have been here all morning waiting for your chance to testify. But we are delighted you have stayed and are here to give us your presentation.

Your prepared statements will all be in the record in full without objection. And we would like to ask each of you to limit the oral presentation to no more than 5 minutes.

Mr. Barnett, if you will pull the microphone close to you, there is a button to push.

**STATEMENTS OF CURTIS H. BARNETTE, CHAIRMAN, BETHLEHEM STEEL CORP., ALSO ON BEHALF OF NATIONAL LEADERSHIP COALITION FOR HEALTH CARE REFORM; ANNE BRYANT, EXECUTIVE DIRECTOR, AMERICAN ASSOCIATION OF UNIVERSITY WOMEN, ON BEHALF OF THE CAMPAIGN FOR WOMEN'S HEALTH; JOHN HOWLEY, ASSISTANT DIRECTOR OF PUBLIC POLICY, SERVICE EMPLOYEES INTERNATIONAL UNION; WILLIAM H. COLEMAN, PRESIDENT, AMERICAN ACADEMY OF FAMILY PHYSICIANS; AND RONALD F. POLLACK, EXECUTIVE DIRECTOR, FAMILIES U.S.A. FOUNDATION**

Mr. BARNETT. Mr. Chairman, Congressman Cooper, it is a great pleasure to be before you once again. I am chairman of Bethlehem Steel Corporation and I appear also on behalf of the National Leadership Coalition for Health Care Reform.

Many adjectives are used to discuss the health care issue. We believe it to be a crisis. There are 39 million uninsured. Our costs are going up dramatically. In the steel industry alone in 1980 to current date our health care costs have gone up some 270 percent, while overall employment costs which health care is a part, have gone up some 165 percent.

Bethlehem Steel Corporation has 160,000 health care beneficiaries. We have 22,000 active employees. Our health care expenses are \$231 million. I think the relevant factor for us is health care expense per health care beneficiary versus active employees. And that is \$10,400 to cover the beneficiaries that are accountable under our health care plan.

We have chosen to analyze and to support health care reform not by supporting or indeed opposing any particular bill, but by identifying what we believe to be the fundamental principles, the fundamental objectives, against which health care reform must take place. And if I may mention only six or seven.

One, universal coverage with standard benefit packages and employer mandates;



Two, cost control with global budgets, spending targets to get health care to CPI inflation rates;

Third, cost shifting must be eliminated;

Four, quality, practice protocols, quality measurement systems;

Five, eliminate administrative waste, and there is ample opportunity to do that;

Six, malpractice reform; and

Seven having Medicare as a primary payer for the elderly.

Bethlehem supports the overall objectives of the President's health care reform program.

With respect to the Cooper legislation, I would make only these observations. I appreciate the opportunity to discuss this. With respect to the Cooper bill in at least three areas, Cooper, as we understand it—and I appreciate that this is an ongoing and a dynamic process—would not provide universal coverage;

Second, it does not aggressively deal with cost control; and

Third, cost-shifting is a serious problem, at least as we understand it today.

It is for all of these reasons that we choose to measure the Cooper legislation and all other legislation against the fundamental objectives that we think must be achieved, and are prepared and anxiously wish to cooperate with the committee, with the Congress and with the administration to achieve the desperately needed health care reform that we think is so essential.

Thank you.

Mr. WAXMAN. Thank you.

[The prepared statement of Mr. Barnette follows:]

STATEMENT OF CURTIS H. BARNETTE, CHAIRMAN AND CHIEF EXECUTIVE OFFICER,  
BETHLEHEM STEEL CORPORATION

Good morning Chairman Waxman and members of the subcommittee.

I appreciate the opportunity to speak before your subcommittee today to share Bethlehem Steel's views and concerns about the Health Care Crisis facing our Nation and the unique opportunity the Congress has—this year—to address this important issue. Health Care Reform is a top priority issue for Bethlehem and, I believe, for all Americans.

The need for comprehensive Health Care Reform—Reform that constrains spending, guarantees coverage to all Americans, and improves the quality of care—is greater now than ever before.

Yes, we have a Health Care Crisis. For those who do not see the crisis, I would point to the following facts:

—39 million Americans have no insurance—the number of uninsured increased by over 2 million between 1991 and 1992.

—One out of four Americans will lose health insurance for some period during the next 2 years.

—Losing or changing a job often means losing health insurance.

—Health care costs are rising faster than other sectors of the economy. Costs are projected to exceed \$1 trillion in 1994, and CBO predicts National health expenditures totaling \$1.68 trillion by the year 2000.

Bethlehem has 21,000 active employees and 160,000 health care beneficiaries—active employees, retirees and their dependents. Bethlehem's health care costs in 1993 totaled \$232 million. Our health cost in 1993 was \$4,453 per active employee for active coverage, but was \$10,386 per active employee for coverage for active and retired beneficiaries.

Bethlehem supports the basic principles of Health Care Reform outlined by President Clinton. We believe that Health Care Reform must be comprehensive—Reform that guarantees coverage to all Americans, constrains spending, and improves the quality of care. The longer we delay needed reforms, the worse the Health Care Crisis will become.

There is no area of public policy that will affect our Nation's future economic growth more than our policy on health care. Our Nation's Health Care System is the most expensive in the world, and without change, it will cripple our ability to compete in the global economy.

While I recognize that the subject of the hearing is Health Care, most respectfully, I would submit that Health Care Reform is only one of the major issues that must be resolved, since it is closely interrelated to other pending key public policy issues.

If you believe, as we do, that the national interest requires a modernized and profitable steel industry in this country, then Health Care, fair trade of steel imports, infrastructure rebuilding, and the responsible application of our environmental laws, are all of great importance.

Our steel industry today is the low cost, high quality producer of steel products for the U.S. market. This has happened through significant restructuring and capital spending. The steel industry today has approximately 169,000 employees, down by almost 58 percent, from 399,000 in 1980. Private companies, not foreign governments, pay the expenses of this restructuring including pension and Health Care costs for deserving retirees and their dependents, and a decreased active workforce has to pay these expenses.

We are still the open market for steel trade, and a net importer of steel products. Foreign subsidies and dumping continue to seriously injure the domestic industry, so that enforcing our trade laws and keeping them strong and effective, is essential.

Rising health care costs are becoming an increasingly important factor limiting the United States' ability to compete in the global market. For example, Bethlehem's shipments total more than 9 million tons of steel. Health Care accounts for 6 percent of its total cost, or \$25 per ton that is not available for necessary investments in plant and equipment, research and development, benefits and employee training. Among our major foreign steel competitors, the United States has the highest per capita Health Care cost. In the United States, this cost is borne principally by the larger employers. Whereas in Canada, Europe, and Japan, the cost of Health Care is spread more equitably among all employers and/or the public.

Health care costs place American steel companies and other domestic companies as well, at a competitive disadvantage. Because steel is an international commodity, and U.S. companies must compete in the global market, this cost disadvantage is simply not sustainable in the long run.

Health Care cost problems in the steel industry are compounded because we provide medical coverage for active employees as well as retirees. Our current workforce is approximately 21,000, and we support Health Care costs for 160,000 Health Care beneficiaries including 63,000 retirees.

Pension and Health Care legacy costs place American industry at a competitive disadvantage because such costs are not borne by our international competitors, but by their governments.

Bethlehem, other steel companies, and the Steelworkers Union have also been actively supporting the Reform principles of the National Leadership Coalition for Health Care Reform. We believe that Reform must address three key issues—first, universal coverage for all Americans, second, workable constraints on increases in Health Care spending, and finally, measures to ensure quality of care.

The Congress has before it President Clinton's Health Security Act, as well as Bills submitted by members in the House and Senate.

The challenge for the Congress in the coming weeks will be to shape a comprehensive Health Care Reform Bill that addresses the Health Care Crisis facing our Nation.

I believe that fundamental Reform at the National level should be consistent with a few key principles addressing cost, access, and quality.

I submit the following principles for your consideration as you draft legislative language.

1. Universal coverage must be addressed. All Americans should have the security of health insurance with a standard benefit package established at the Federal level.

We support the principle that working Americans should be covered for health insurance through the workplace—with appropriate subsidies for small business and that non-working Americans, regardless of their circumstances, should be covered through broad community programs or Health Alliances.

2. Costs control must be addressed. Aggregate growth in our Nation's Health Care System must be controlled. We support the use of global budgets or spending targets to bring the annual escalation in Health Care costs down to an acceptable level (the CPI inflation rate).

3. Cost shifting must be eliminated. Legislation is needed to ensure that public and private payers pay the same for Health Care. All payer regional reimbursement schedules for provider fees should be established.

4. We must ensure that we maintain the quality of Health Care with the use of appropriate tools such as practice protocols, technology assessment, quality measurement systems, and National Quality Data Bases.

5. Administrative waste must be eliminated through the use of standard identification cards and claim forms and electronic processing.

6. Malpractice reform is needed to reduce costs associated with medical malpractice suits and defensive medicine.

7. Medicare must remain as the primary payer for the elderly.

Bethlehem will be applying these key principles in evaluating each of the Health Care proposals that are before the Congress.

We commend Congressman Cooper for his leadership on Health Care Reform.

While the Cooper Bill, H.R. 3222, is consistent with a few of the principles, it does not adequately address the most important principles of Universal access and cost control.

H.R. 3222 would not achieve Universal coverage. Bethlehem believes that Universal coverage is a crucial element of Health Care Reform. Having access to Health insurance is good, but it is not enough. We should make sure that all Americans actually have coverage.

Second, H.R. 3222 is not aggressive enough on cost control. It relies on competition to achieve cost control and we do not believe this is sufficient. I urge the subcommittee to report out legislation that includes the expenditure targets and rate setting to insure cost control. Experience in the United States and elsewhere in the world has made it clear that rate setting is an effective tool for controlling cost.

In its current form, H.R. 3222 would cut the rates of growth in Medicare and Medicaid, thereby inviting providers to make up for the lost revenue by raising premiums paid by businesses and other private payers—thus continuing today's cost shifting which needs to be addressed by Health Reform.

I am encouraged by the clear signs that Republican and Democratic leaders in the Congress are intent on achieving meaningful Health Care Reform. We must successfully meet the challenge, and we must do so in 1994. Bethlehem is anxious to work with your subcommittee and the Members of Congress and the administration as you work to achieve comprehensive Reform of our Health Care System.

I thank you for the opportunity to meet with you today.

Mr. WAXMAN. Mrs. Bryant.

#### STATEMENT OF ANNE L. BRYANT

Ms. BRYANT. Thank you for the opportunity to address this committee on the Managed Competition Act. I am Anne Bryant, Executive Director of the American Association of University Women, but I am speaking today on behalf of the Campaign for Women's Health, which is a broad-based coalition of 90 national, State and community-based organizations representing more than 8 million individuals committed to ensuring that women's health is fully addressed in the national health care system.

While I am not an expert on the many nuances of health care reform, AAUW's 135,000 members in 1,750 communities care a great deal about this issue; and our long history of interest in and advocacy on behalf of women's health goes back to 1885, in fact, when we produced our first research that was a major study to counteract the work of Dr. Edward Clark, who claimed that higher education adversely affected women's mental and reproductive health. Needless to say, it was not hard to disprove his theories.

We are pleased that the Cooper-Grandy bill would ensure that every American would have the right to purchase health care insurance, but universal access to health care does not necessarily translate into universal coverage, an issue that has been talked about greatly this morning. Just because health coverage is available to the public does not mean it will be affordable to all.



We believe this proposal falls short in three critical areas: first, guaranteeing universal coverage; second, providing comprehensive benefits packages for women; and three, ensuring access to the variety of providers in health care delivery settings that women require.

The first is universal coverage. AAUW and the Campaign for Women's Health are convinced that national health care reform must provide universal coverage for every individual.

Although the Cooper-Grandy bill makes certain reforms in the insurance industry in order to provide greater access to health care coverage, it does not address the issue of affordability for those individuals in low-paying jobs. Women are two-thirds of the part-time and temporary workers and hold the majority of low-paid jobs in the service, sales and household industries, occupations where many times these benefits have historically not been provided and for whom buying the insurance is an impossibility. Congress cannot ignore the fact that cost is the major barrier to obtaining needed health care and preventive services.

Although the bill addresses Medicaid-eligible Americans, if it were to pass, women on Medicaid will lose current support services such as transportation, child care and translation assistance. These vital, enabling services are the only way many low-income women are able to get access to the care they need.

The second area is comprehensive benefits. In an attempt to pass legislation and get the votes you need, the proponents of this bill are finessing the tough decisions regarding health care services and which of those will be provided. We are not willing to risk leaving those choices to the political vagaries of a National Health Board, a politically appointed decision-making body that does not require representation of women and women's health care experts.

Any national health care plan must define its benefits in the legislation in order to ensure those benefits are secure. It is particularly important that women receive full coverage for primary and preventive care, long-term care, reproductive health care counseling, and including services such as contraception, prenatal and maternal care and abortion.

Mr. WAXMAN. Ms. Bryant, there is a vote on the Floor that none of us knew about because the lights are not working here. We are going to recess, vote, and then come back.

[Brief recess.]

Mr. WAXMAN. The meeting will come back to order.

Ms. Bryant, please conclude.

Ms. BRYANT. I am assuming I get my time. I noticed that the word "abortion" had you all running out of the room. I will pick up at the sentence where I left off.

We believe it is particularly important that women receive full coverage for primary and preventive care, long-term care, reproductive health care and counseling, including services such as contraception, prenatal care, maternal care and abortion. Reproductive health care is often a woman's entry point into the health care system and may be the only form of primary care that she receives.

I was pleased this morning to hear Mr. Cooper's response to Mr. Synar's question, which opened the way for a predetermined set of

benefits. This must include reproductive health care. It cannot be left to politicians and a separate vote in Congress.

We are greatly disturbed by proposals to exclude abortion services from any standard benefits package and to make a rider available to those women who want coverage for this service. Such a proposal discriminates against women by making a medical procedure specific to women an "extra" in their health care coverage. Simply, it is unethical to force women to buy additional coverage year in, year out throughout their reproductive lives for a service they hope they will never need and could not possibly anticipate or plan.

Moreover, many women already have coverage for this service through their private and Federal insurance plans. This is not health care reform. Under this proposal, women who now have insurance coverage for abortion services would lose that critical benefit.

The third and final area of concern is the range of providers and setting. AAUW and the Campaign for Women's Health believe that the delivery of health care services is just as important as the services themselves. If a woman cannot get access to these services, they are of little benefit.

We commend the sponsors of this bill for its training provisions that will increase the number of primary care providers, including physician assistants, health educators, nurse practitioners and nurse midwives, many of whom play a significant role in providing women with needed care in community-based settings.

We are also pleased that the bill would make grants available to community-based clinics to improve access to coverage in underserved areas. However, we are concerned that the bill does not reach all underserved populations because it does not specifically require reimbursement of services provided in settings of particular importance to women such as family planning clinics, school-based and school-linked clinics. To exclude these settings is a glaring omission because they are frequently the only places that many girls, particularly those from low-income families, receive critical health care services.

Two years ago the AAUW Educational Foundation released the AAUW report, *How Schools Shortchange Girls*. This ground-breaking report documented pervasive bias against girls in schools, but what the media missed was a major section in the report which outlined a distressing finding that in most schools scant attention and resources are given to girls' health needs.

Let's not perpetuate this failure to address girls' health. Services provided in school-linked settings would address many problems that disproportionately affect the health and educational performance of girls, such as eating disorders, depression and suicide, sexually transmitted diseases and pregnancy.

One of the major goals of national health reform is to respond to the inequities in the current health care system. This is an excellent opportunity to remove barriers that women face in obtaining comprehensive health care.

While we applaud the Managed Competition Act for its attempt to improve access to health care for all Americans, it falls short of addressing women's health care concerns.

In summary, AAUW and the Campaign for Women's Health are committed to ensuring that women are not left behind in this reform process.

Thank you.

Mr. WAXMAN. Thank you.

[The prepared statement of Ms. Bryant follows:]



## STATEMENT OF AMERICAN ASSOCIATION OF UNIVERSITY WOMEN

Chairman Waxman, thank you for the opportunity to testify before this committee about the impact of HR 3222, the Managed Competition Act, on women's health care concerns. I am Anne Bryant, Executive Director of the American Association of University Women (AAUW), an organization of 135,000 members in 1,750 communities nationwide. I am testifying today on behalf of the Campaign for Women's Health, a broad-based coalition of 90 national, state, and community-based organizations representing more than eight million individuals committed to ensuring that women's health care needs are fully addressed in national health care reform.

While I am not personally an expert on health care reform, AAUW has a long history of interest in and advocacy on behalf of women's health. From its beginning in 1881, AAUW has worked to improve the health and welfare of all people. In 1935, an AAUW resolution called for "more extensive research to assist in the scientific knowledge needed for maintaining health." Women's health concerns in health care reform are currently a top AAUW public policy action priority.

Although we are pleased that HR 3222 would ensure universal access to health care for all Americans, this bill provides only a partial solution to the health care problems facing women today. We believe that this proposal falls short of guaranteeing universal coverage, a comprehensive benefits package for women, and access to the variety of providers and settings that women require.

### Universal Coverage

AAUW and the Campaign for Women's Health are committed to ensuring that national health care reform provides universal coverage for every individual. This is particularly important to women. The current practice of tying health insurance to full-time employment has resulted in many women falling through the cracks. Two-thirds of part-time workers are women, and women are more likely than men to be employed in temporary positions, in small businesses, and in service, sales and household jobs where benefits are frequently not provided. Due to family caregiving responsibilities, women's work patterns are more likely to be episodic than those of men. That results in inconsistent coverage and vulnerability to pre-existing conditions clauses, including loss of pregnancy and maternity benefits. Because women are the primary caregivers in most families, they are frequently dependent on their husbands' insurance coverage, which they lose upon divorce or widowhood.

The 1993 Commonwealth Fund Women's Health Survey found that among the uninsured in this country, women are more likely than men not to get the care they need: 36 percent of the women surveyed, compared to 23 percent of the men, reported not receiving needed care in 1993. The January 1994 report prepared by the Women's Research and Education Institute revealed that women account for 69 percent of the 10.8 million Americans age 15 to 44 for whom out-of-pocket health expenditures represent more than 10 percent of their income.

Under the Managed Competition Act, individuals may voluntarily purchase health insurance coverage, with or without an employer contribution. This proposal for universal access will leave many women outside the health care system. It will not reduce the burden of health care costs on individuals and their families, which constitute a major barrier to obtaining needed care and preventive services.

The bill's provisions for reducing premiums and cost-sharing for low-income individuals may not be sufficient to remove barriers to poor women's access to health care. According to the WREI study I have already mentioned, 55 percent of women below the poverty line currently do not receive preventive care. "Universal access" in HR 3222, by not substantially lowering premiums and out-of-pocket costs, is an inadequate solution to this problem. Medicaid-eligible women who must obtain coverage for acute services through health plan purchasing cooperatives under this bill will lose current Medicaid support services such as transportation, child care, and translation assistance. These enabling services are the only way many low-income women are able to obtain the care they need.

#### Comprehensive Benefits

AAUW and the Campaign for Women's Health are dedicated to ensuring that women receive legislatively-defined comprehensive benefits that include the full range of reproductive health



services, an emphasis on primary and preventive care, and comprehensive long-term care. HR 3222's failure to outline a guaranteed comprehensive benefits package will also leave women without access to all the health care services they need over their lifetimes.

By leaving the determination of covered benefits to a National Health Board, the Managed Competition Act makes coverage for the health care concerns I have outlined subject to the political vagaries of an appointed decision-making body. Women have seen the results of panels of policy experts defining our health care needs. The General Accounting Office has reported that the federal government, the major investor in health research, spends a disproportionately small amount of of its \$8 billion annual budget for studies of diseases and conditions unique to, more prevalent, or more serious in women. Women are excluded from or underrepresented in clinical trials, leaving physicians unable to determine whether the results from studies can be extrapolated to women.

It is particularly important that women receive full coverage for reproductive health care and counseling, including services such as contraception, prenatal and maternal care, diagnosis and treatment for sexually transmitted and reproductive tract diseases, and abortion services. Reproductive health care is often the first type of care a woman seeks--her entry point into the health care system--and may be the only form of primary care she receives.

We are greatly disturbed by proposals to exclude abortion services from the standard benefits package and to make a rider available to those women who want coverage for this service. Such a proposal discriminates against women by making a medical procedure specific to women an "extra" in their health care coverage. This requires women to pre-pay for a service they cannot anticipate needing and for which many currently have coverage through private and federal insurance plans. Under this health care reform proposal, women would actually lose a benefit.

Insufficient funding for breast cancer research has resulted in a lack of information on the causes, diagnosis, and treatment for this leading cause of death for women ages 35 to 52. The National Health Board would determine coverage for diagnostic and treatment procedures for breast and other cancers specific to women, including the frequency of mammograms and Pap Smears for women of different age groups. Given the current controversy over the effectiveness of mammography screening for women under 50, we are concerned that early detection of these deadly diseases might be thwarted by cost-saving efforts. Any attempts to impose the costs of these screening services on women will disproportionately burden low-income women and women of color, who are already more likely to die of breast cancer due to delayed diagnosis.

The future of research on women's health care concerns is already in jeopardy. Women are currently underrepresented in both senior research and policymaking positions that determine the

course of health care research. HR 3222 not only vests these same experts with the power to define those services to which women will have access under health care reform, but the bill contains no provisions for guaranteeing representation of women and women's health experts on the National Health Board.

#### Range of Providers and Settings

AAUW and the Campaign for Women's Health are committed to ensuring that under national health care reform women will be able to obtain covered services in hospital and outpatient settings, the home, community-based clinics, school-based clinics, skilled nursing facilities, long-term care settings, and hospice facilities. To guarantee that the reformed health care system provides access for all women, services must be available from the full range of health care providers and in community settings that are appropriate and convenient for women and girls. The creation of a health care continuum, from early childhood to old age, will require putting services where women and their families can take advantage of them.

We commend the sponsors of HR 3222 for its training provisions intended to increase the numbers of primary care providers, including physician assistants, health educators, nurse practitioners, and nurse midwives, many of whom play a significant role in providing women with needed care in community-based settings. We are also pleased that the bill would make grants available to community-based clinics to improve access to coverage



in underserved areas. We are concerned, however, that the bill does not specifically require reimbursement of services provided in settings of particular importance to women, such as family planning clinics and school-based or school-linked clinics. These two settings are frequently the only places many women and girls, particularly those from low-income families, receive critical health care services.

In 1992, the AAUW Educational Foundation released The AAUW Report: How Schools Shortchange Girls, highlighting a variety of issues that have an impact on the opportunities of girls to succeed in school and beyond. Among them were health needs currently given little attention and resources in most school systems. While coordination of services and health education would benefit all students, it has particular relevance to the lives and educational experiences of girls. Services provided in a school-linked setting would address many problems that disproportionately affect the health and educational performance of girls, such as eating disorders, depression and suicide, sexually transmitted diseases, and unintended pregnancy.

### Conclusion

One of the major goals of national health reform is to respond to inequities in the current health care system. This is an excellent opportunity to remove specific barriers that women face in obtaining comprehensive health care. While we applaud the Managed Competition Act for its attempt to improve access to health care for all Americans, it does not succeed in addressing women's health care concerns. It is of the utmost importance that any health care reform passed by this Congress bring an end to the inequitable treatment of women in the health care delivery system. AAUW and the Campaign for Women's Health are committed to ensuring that women's health care concerns are not left behind in this reform process. I thank you for the opportunity to further that goal by speaking before you today.

Mr. WAXMAN. Mr. Howley.

### STATEMENT OF JOHN HOWLEY

Mr. HOWLEY. I would like to thank you, Chairman Waxman and the other members of the subcommittee, for this opportunity to testify on behalf of the 1 million members of SEIU. I am here today to speak in opposition to the Managed Competition Act of 1993, H.R. 3222.

SEIU is opposed to this legislation because it does not meet our principles for universal coverage regardless of health or employment status, real cost control, quality improvement, and fair and equitable financing and protection for health care workers.

H.R. 3222 fails this test. It creates the illusion of reform without the substance.

The Managed Competition Act is not really, however, a painless placebo that simply maintains the status quo. In many ways, we believe it would actually make things worse for hard-pressed, middle-income, working families. For example, the bill would create tax incentives for employers to shift even more of the burden of health insurance onto the backs of workers.

Over the past year, more than 2 million people have lost their health insurance, raising the number of uninsured to 39 million. One out of every four Americans will lose their health insurance for some period during the next 2 years. It is very clear that our employer-based health insurance system is unraveling rapidly before our eyes.

Our local unions continue to report that employers have been trying to scale back the scope of insurance coverage and place greater restrictions on its use. We see this effect every day. For example, we represent workers who are employed by service contractors. It is very easy for one service contractor to underbid another simply by not providing health insurance to their low-wage employees.

The Managed Competition Act would not require employers to make any contribution to their employees' health insurance costs. This would leave millions of Americans unable to afford insurance.

It is remarkable that the Managed Competition Act relies on complete faith in the idea that with a little tinkering, market forces can be made to keep health care costs under control. During the 1980's, which was the era of deregulation in health care and other markets, we saw greater price increases than ever before.

We are not opposed to using the market forces, where appropriate, to give consumers more choices. We simply think that there has to be a guarantee to working people that they are going to be protected in the event that those market forces don't work. That is the main difference between the Health Security Act and the Managed Competition Act. The Health Security Act says, let's use market forces to control costs, but if they don't work, let's back them up with caps on the cost increases.

I think that the chairman was right to zero in on the tax cap proposal, which we believe is designed to put the burden of the risk of continued increase in health inflation and health spending right on the consumer. It is accurate to say that the employers will simply limit their contribution to whatever the tax cap is, and employ-

ees will be stuck should health spending rise faster than the tax cap itself.

As for the distributional impact of a tax cap, we did a study last year which looked at what would happen if you capped the so-called "deduction" that families could take. We found that 75 percent of the tax increase would be paid by families earning less than \$75,000. The mechanisms on these tax caps may vary, but the distributional impact is there.

If you ask Mr. Iacocca or any of his successors to pay another 50 bucks a month for health insurance, he is not even going to blink. But if you ask the average taxpayer to pay an extra 50 bucks for health insurance, that makes a big difference to them. You can't separate the issue of the tax cap from the benefit package.

What is the benefit package going to be? I have heard supporters of the Cooper bill say the Health Security Act benefit package is a Cadillac package. Let me point out that the Health Security Act leaves families exposed to up to \$3,000 a year in health costs and that is the standard throughout both the union and nonunion sector these days.

So if that is a Cadillac package, what then are we talking about? Usually a Chevrolet costs a third to a quarter of what a Cadillac costs, so presumably we are talking about bare-bones catastrophic coverage here. That would mean setting the tax cap very low and shifting a good deal of the cost onto the backs of the workers.

I think that without an employer mandate that requires all employers to cover their workers, we will continue to have competition among employers on the basis of who provides coverage and who doesn't.

The impact of the employer mandates—the issue of the disemployment effects, I think is a red herring. The Health Security Act would require a 15-cent-an-hour increase. President Bush signed a 90-cent-an-hour increase in the minimum wage without any disemployment effects.

Thank you.

Mr. WAXMAN. Thank you very much, Mr. Howley.

[Testimony resumes on p. 137.]

[The prepared statement of Mr. Howley follows:]



**TESTIMONY OF JOHN HOWLEY  
ASSISTANT DIRECTOR OF PUBLIC POLICY**

**SERVICE EMPLOYEES INTERNATIONAL UNION, AFL-CIO, CLC**

My name is John Howley and I am the Assistant Director of Public Policy for the Service Employees International Union. With over one million service-sector workers in the United States, Canada and Puerto Rico, SEIU is the fourth largest union in the AFL-CIO, and the largest union representing service workers.

SEIU members come from both the public and private sectors and include 450,000 health care workers who work in acute care hospitals, nursing homes, mental hospitals and other health care facilities. On their behalf, I would like to thank Chairman Waxman, and the other members of the subcommittee for this opportunity to testify on one of the most critical issues facing our nation today. Let me also take this opportunity to applaud the chairman for your outstanding leadership in this area over the years.

Our members don't need charts and graphs or expert pronouncements to understand that there is a crisis in our health care system. Over the last decade, health care has been the number one issue at the bargaining table. Our members have fought hard to hold on to their health insurance, often foregoing wage increases and benefit improvements to maintain coverage for themselves and their families. They have faced greater out-of-pocket costs and declining choices, as employers have tried to restrict where and when they can see a doctor.

While disagreements over health care issues have made collective bargaining more contentious than it otherwise would have been, labor and management have also worked together to pioneer new cost containment strategies such as utilization review and managed care. While these measures showed some short-term success, they were unable to blunt the long-term rise in costs. Only system-wide reform can provide the relief that workers and their employers need.

I am here today to speak in opposition to the Managed Competition Act of 1993 (H.R. 3222). SEIU is opposed to H.R. 3222 because it does not meet SEIU's principles for reforming the health care system. These principles include universal coverage regardless of health or employment status, comprehensive benefits, real cost control, quality improvement, fair and equitable financing, and protection for health workers. These are the criteria by which we judge the various health care reform proposals that have been put forward. Unfortunately, H.R. 3222 completely fails the test. It creates the illusion of reform without the substance.

The Managed Competition Act is not merely a painless placebo that simply maintains the status quo. In many ways, it would actually make things worse for middle-class families. The bill creates tax incentives for employers to shift more of the burden of health insurance onto the backs of workers. Its reliance on community rating as a substitute for cost control would actually raise premium costs for the majority of businesses, without any compensating slowdown in the rate of increase in health costs.

In my testimony today, I want to address three issues in detail: the failure of the Managed Competition Act to guarantee universal coverage; the reasons why the Act would not successfully control health care costs; and the likely negative impact of this proposal on the nation's public health system.

## **Universal Coverage: No Compromise**

It should be a source of shame to us that in the richest nation on earth there are 39 million people without any form of health insurance whatsoever. Millions more are underinsured and often do not discover the crucial gaps in their coverage until it is too late. In addition to the high cost of health insurance, many individuals and families are denied coverage because their employer does not provide it or because of pre-existing conditions that the insurance company refuses to cover.

Over the past year, more than two million people have lost their health insurance, raising the number of uninsured to 39 million. One out of every four Americans will lose their health insurance for some period during the next two years. Many of our members report that their employers have been trying to scale back the scope of their insurance coverage and place greater restrictions on its use.

Unlike the Health Security Act, H.R. 3222 would not require employers to make any contribution toward their employees' health insurance costs. This would mean that millions of Americans would still be unable to afford insurance. Workers could still lose their insurance if they lost their jobs or if they changed jobs. By failing to guarantee universal coverage, the Managed Competition Act fails to provide working families with the health security they so desperately need.

## **Cost Control: Why the Market Can't Do it Alone**

A remarkable aspect of the Managed Competition Act is its complete faith in the idea that, with a little tinkering here and there, market forces would be capable of keeping health care costs under control. This scenario flies in the face of our experience over the last decade with deregulation in the health care industry. Reagan-era reliance on market forces brought us the highest rates of medical price inflation ever. This does not mean that SEIU is opposed to making the market for health insurance more competitive and responsive to consumer needs. We simply feel that these measures alone will not bring health care costs under control.

In our view, the cost control strategy in H.R. 3222 suffers from seven major weaknesses:

- Price competition between plans won't necessarily bring costs down.
- "Managed Care" plans may not be more cost-effective.
- Voluntary purchasing cooperatives will be undermined by adverse selection.
- Insurance reform without cost control may raise costs for those with insurance.

- Capping the employers' tax deduction for health insurance will increase costs for middle-class families.
- Allowing the benefits package to be determined later makes it harder to assess the likely effectiveness of cost control measures.
- The lack of universal coverage will lead to higher costs for those with insurance.

I want to deal with each of these points in turn.

### *Competition Between Plans Won't Necessarily Bring Costs Down*

A key assumption of the Managed Competition Act is that the creation of a more competitive climate for health insurance will lead to premium reductions. The experience of SEIU Local 1000, the California State Employees Association, suggests that competition may not work as advertised.

Local 1000 members receive their health benefits through the California Public Employee Retirement System (CalPERS). For most of the 1980s, CalPERS had most of the elements that proponents of managed competition argue must be present if the system is to work. Over 20 plans, most of them HMOs, competed with each other for enrollees. The vast majority of enrollees are in managed care plans, such as HMOs or PPOs. There were significant differences in the prices charged by plans and the state government contributed a fixed amount per worker (although the amount was not tied to the lowest cost plan), so consumers had an incentive to enroll in lower cost plans.

Despite the apparent existence of a competitive market, CalPERS actually fared worse than other employers nationally in managing health care costs during the 1980s. According to Lewin-VHI, average family premiums for the nation as a whole increased 9.4 percent annually between 1982 and 1992, compared to 12.9 percent for CalPERS fee-for-service plans and 9.8 percent for CalPERS HMO plans.

### *Managed Care Has Had Disappointing Results*

The drafters of the Managed Competition Act assume that moving workers into "managed care" health plans can play a major role in keeping health care costs under control. Our members' experience is that while managed care, UR, and other innovations can produce "one time" savings, they haven't kept costs under control over the long term.



For example, about 6 years ago, members of SEIU Local 79, which represents building service and health care workers in Detroit, opted to switch from their indemnity plan to an HMO to save money. However, within three years the cost of the HMO equalled that of the previous indemnity plan. In the fourth and fifth years, the cost of the HMO was actually higher than the indemnity would have been and the workers also began to lose benefits. At the end of the fifth year, the workers dropped the HMO and went back to the original indemnity plan.

In the early 1980s, SEIU Local 668, which represents social service workers in the state of Pennsylvania, negotiated with employers over a number of cost-control provisions (second surgical opinion, pre-admission certification, generic drugs, etc.) that were instituted for most contracts. These measures were successful for three or four years. By the time the contracts were up for renegotiation, costs had begun to rise again and employers were asking for further concessions. The next round of negotiations saw the introduction of HMO and PPO options, as well as increased premium sharing. Despite the introduction of all of these measures, costs continue to rise at the same pace.

Surveys of employers, consumers, and health care industry leaders have consistently found that managed care has not lived up to its promise. For example, a 1991 American Hospital Association survey of chief executives of voluntary health insurance purchasing cooperatives found that only 10 percent agreed that HMOs had been successful in controlling health care costs. Only 22 percent agreed that PPOs had been successful.

I don't want to give the subcommittee the impression that our members have uniformly negative attitudes toward HMOs and PPOs. In many cases, we have had to fight hard to get employers to provide these options. Often, managed care allows us to preserve benefits without increasing the cost to our members. We realize that no health plan is going to suit every single person and we want to give our members the widest range of choices that we can. What we object to is attempts by employers to make an HMO or a similarly restrictive plan the only option available to workers.

But we also recognize that, in most cases, savings from managed care plans come from the discounted rates that those plans pay to providers. Providers make up the difference by shifting those costs onto other payers with less market power. Cost shifting among payers by providers should not be confused with overall cost control.

#### *Adverse Selection Will Undermine Voluntary Health Plan Purchasing Cooperatives*

A central feature of the Managed Competition Act is the Health Plan Purchasing Cooperative (HPPC), which would offer group purchasing power to employers with 100 or fewer employees. Employers would be required to offer employees coverage through the HPPC, but they would not be required to make any contribution to the cost of that coverage.

The lack of such a mandate is almost certain to lead to adverse selection among workers in the HPPC. Those employees who are more likely to be sick will purchase coverage, while those who are relatively healthy may go without coverage. This, in turn, will raise costs for those who do choose to purchase coverage. The result could be a vicious cycle that could well destroy the HPPC as a meaningful entity. If small employers are unable to realize lower premiums as a result of their membership, then they would be no more likely to purchase coverage for their workers than they are now.

With the help of the Robert Wood Johnson foundation, a number of states have experimented with purchasing cooperatives for small business that also operate on a voluntary basis. While some small employers did obtain coverage through these arrangements, even the most successful project only enrolled 17 percent of employers who previously had not offered insurance. The Arizona Health Care Group, one of the longest running projects, only succeeded in enrolling 939 small firms, for a total of 3,093 covered lives, during the first three and half years of its existence. Similar experiments in other states proved similarly disappointing.

The results of the American Hospital Association's 1991 survey of chief executives of voluntary purchasing cooperatives were also discouraging. Less than half of those surveyed agreed that the cooperative had made a difference in controlling health care costs in their community.

*Insurance Reforms Without Cost Control Could Make Things Worse for Businesses and Consumers*

The Managed Competition Act proposes to regulate the insurance market in ways that would make it easier for those without insurance to obtain it. These provisions, which are common to most health care reform bills, include prohibiting pre-existing condition exclusions and requiring insurers to community-rate instead of experience-rate.

Taken alone, these reforms would raise costs for many businesses who are currently providing insurance. Some of those businesses might choose to drop coverage, potentially creating a vicious circle that would ultimately undermine the entire health insurance market.

While insurance reforms are clearly necessary to eliminate discrimination in the health insurance market, they must be implemented in tandem with cost control provisions that ease the burden on those businesses and consumers whose costs will go up under reform. To do otherwise creates the potential for a political backlash that could undermine the entire health care reform effort.

### *Taxing Health Benefits Will Hurt Middle-Class Families*

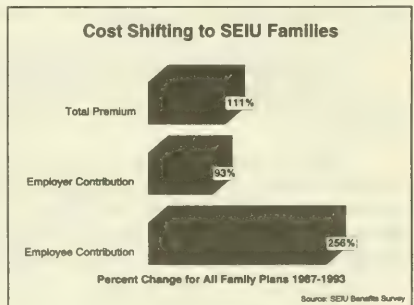
A key feature of the Managed Competition Act is a cap on the employer tax deduction for health insurance costs. The bill would limit the deduction to the price of the lowest cost plan. While this allows supporters of the Act to claim that no one's taxes are being raised, they clearly assume that employers will respond by limiting their contributions for health insurance to the price of the lowest cost plan. This, in turn, is meant to make workers more "conscious" of the cost of their benefits, encouraging them to enroll in cheaper health care plans.

The bottom line is that whether the tax is levied on employers or workers, it is the workers who will end up footing the bill. They will have to pay more, potentially hundreds of dollars more, to maintain their health insurance coverage. If they cannot come up with the money, they will be forced to enroll in cheaper, possibly substandard plans which will almost certainly limit their ability to choose their doctors.

As someone who has personally negotiated hundreds of contracts, I can tell you that our members are *very* conscious of the cost of health care. Health care is the number one issue at the bargaining table and the number one cause of strikes. Workers are paying a greater share of the premium than they used to, they are paying more out-of-pocket for health care services, and they have given up wage increases in order to preserve their health benefits. It should also be noted that non-union workers aren't able to "shop around" for health plans because it is the employer who chooses what plan to offer.

We have been tracking the cost experience of plans that cover our members since 1987. Over the past six years, SEIU family premium contributions have risen an astounding 256 percent, nearly three times as fast as the increase in employer contributions, which rose 93 percent. Workers with family coverage now pay almost \$1,000 a year on average in premiums payments alone, up from just \$270 just six years ago.

In some cases these premium increases can be financially devastating. SEIU Local 100 represents 200 community mental health workers in Lafayette and West Bank, Louisiana. Most of these workers make around the minimum wage. Last November, the employee contribution was raised from \$20.49 a month to \$54.74 a month. Most of those workers had to drop their coverage.

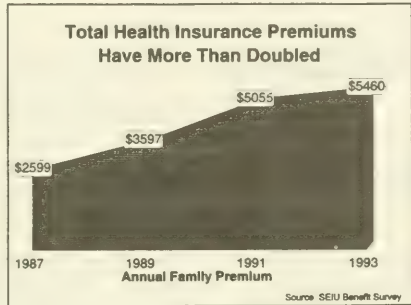




Premium payments are only a part of a worker's total health care bill. Workers also have to meet their deductibles, as well as foot the bill for copayments on physician's visits, prescription drugs, and hospital stays. Family deductibles for SEIU members have increased 16 percent over the past six years. Copayments for major medical expenses have risen from 16 percent of the cost of the service in 1989 to 18 percent in 1993.

Despite dramatic increases in employee cost-sharing, health premiums have continued to climb at double-digit rates. Today, total SEIU family premiums average \$5,460 -- more than double the average premium of \$2,600 just six years ago. I want to emphasize that the reason that premium levels for SEIU plans are so high is *not* because our members have "cadillac plans." In fact, first dollar coverage is increasingly rare. SEIU members are concentrated in some of the highest cost areas of the country, such as the Northeast, the industrial Midwest, and California, and many work for smaller employers and industries, like health care, that insurers have designated as high-risk.

Experience provides little support for the assumption that shifting even more of the burden of health care costs to workers will help keep costs under control. Heightened consumer sensitivity to costs failed to slow health care spending in the 1980s. In this context, it is clear that capping the employer deduction for health insurance costs will merely add insult to injury.



#### *The Benefits Package Cannot Be Considered Apart From the Rest of the Plan*

The Managed Competition Act also fails to establish a uniform package of benefits to which all Americans would be entitled. The establishment of such a package is left to a newly-established Health Care Standards Commission. Once the Commission determines the benefit package, Congress may vote it up or down, but may not amend it.

SEIU is strongly opposed to this process. The scope of benefits, and how the costs are to be shared by government, employers, and consumers are the central decisions to be made in comprehensive reform. They should be made by the Congress, not deferred to an appointed Commission.

It is also difficult to imagine how accurate estimates of the revenue gained by the bill's "tax cap" proposal can be generated if we do not know the particulars of the benefit package. It will also be difficult to determine just how many middle-class families are likely to be paying because of the "tax cap."

Clearly, the decision by the drafters of the Managed Competition Act to defer the hard decisions about the scope of the benefit package has political benefits. This sleight of hand has allowed some backers of the legislation to attack the supposed "generosity" of the Health Security Act's benefit package while allowing them to remain unspecific about what they would cut.

### *Universal Coverage is the Key to Controlling Costs*

A key failing of the Managed Competition Act is its rejection of universal coverage. The growing number of uninsured has contributed to rapidly rising health care costs. Uninsured persons still seek care, often through very costly and inefficient mechanisms. These costs are passed on by providers to their paying customers, the insured population.

Many employers who are currently providing insurance are paying more than their fair share because they are paying to cover the uninsured and paying to provide coverage to the working spouses of their employees. In essence, they are subsidizing their competition. A 1991 National Association of Manufacturers study found that the cost of providing coverage to working dependents increases costs for firms providing insurance by 20 percent.

The growing disparity in employee compensation costs between firms that do provide insurance and those that don't is beginning to generate serious distortions in the labor market. The dramatic increase in the number of part-time and contingent employees, which constitute half of all new jobs created during the past year, is being driven in large part by the desire of employers to avoid the cost of health care benefits. Firms that do provide health benefits to all of their employees are increasingly finding themselves at a competitive disadvantage.

For example, SEIU Local 750 represents building service workers in Orlando, Florida. One of the contractors whose employees Local 750 represented lost a contract with Delta Airlines that it had held for over eight years to a non-union contractor. The non-union contractor did not provide health insurance for its workers, and thus was able to underbid the unionized contractor.

If we can agree that universal coverage is an imperative, the question becomes how to provide it. The strength of an employer mandate approach is that it builds on the existing system. Nearly two-thirds of the non-elderly have employment based coverage. Among the 39 million Americans who lack insurance, 85 percent belong to families that include an employed adult. A system that required all employers to contribute to the cost of health insurance for their workers would reach the vast majority of the uninsured. Unfortunately, the backers of the Managed Competition Act have rejected an employer mandate and even the concept of universal coverage.

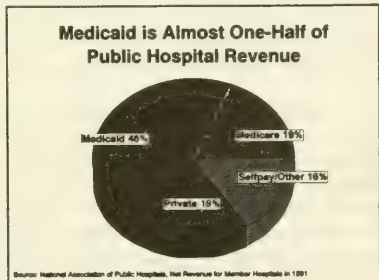
It is ironic that the backers of the Managed Competition Act style themselves as supporters of "pure" managed competition, as opposed to the modified form of managed competition that is found in President Clinton's Health Security Act. The Jackson Hole Initiative, which is widely regarded as the basis for a number of Congressional managed competition proposals, *specifically includes an employer mandate*. Even the drafters of the Jackson Hole proposal understood that, short of a totally government funded plan, there is no other way to guarantee universal coverage.

While the Act provides some subsidies for low-income households, a family earning \$30,000 could be stuck with the bill for a \$5,000 policy. A recent New York Times editorial commented: "Mr. Cooper calls that universal access; we call it merciless" (Jan. 16, 1994).

The bottom line is that no other nation with a national health care system relies solely on the market to control health care costs. While the specific regulatory tools vary from country to country, all nations with such systems have imposed some kind of limit on the amount they spend on health care. For all of the reasons that I have outlined above, SEIU feels that the advocates of unbridled managed competition are dangerously mistaken.

### The Impact of the Managed Competition Act on Public Health Workers

One final issue I want to deal with today is the impact of the Managed Competition Act on health care workers, particularly those in the public sector. The Act would eliminate the Medicaid program in favor of a system of federal subsidies that would allow low-income families to purchase coverage through Accountable Health Plans. While the drafters of the Managed Competition Act should be given some credit for wanting to make it easier for low-income families to obtain insurance, their solution would devastate the public health infrastructure, particularly public hospitals, on which those families depend.





State Medicaid programs currently pay out over \$25 billion annually to hospitals for inpatient and outpatient services. The National Association of Public Hospitals estimates that Medicaid constitutes just under half of net revenues for public hospitals. The elimination of Medicaid could be financially devastating for safety-net providers, and would lead to the kind massive layoffs of public sector health care workers that we've seen in the steel and auto industries over the past decade.

Advocates of H.R. 3222 are likely to argue that the extension of health insurance to all of those under the poverty line will actually increase the amount of funds flowing to providers in underserved areas. But there are no requirements in the bill that Accountable Health Plans (AHPs) contract with public hospitals or other essential community providers in underserved areas. Lacking such a requirement, it is almost certain that AHPs will seek to prevent their enrollees from using those facilities because of their historically higher costs. While the bill does allow states to mandate that AHPs operate in underserved areas, it does not include any provider protections. If they are unable to obtain services from providers in their communities, enrollees in underserved areas may have to travel much farther to obtain services and may postpone needed primary care. The result will be higher costs for everyone.

The Managed Competition Act also includes no protections for health care workers who could lose their jobs as a result of the kind of unbridled competition between plans and providers envisioned in the Act. Our members recognize that the health care industry is going through a massive restructuring. They support a reform of the health care system that places the patient's needs at the center and strives to eliminate the inefficiencies that have contributed to rapidly rising costs. But our experience has been that when administrators and managers try to cut costs in response to competitive pressures, they tend to take the low road of layoffs and wage cuts rather than the high road of reorganizing work and retraining workers.

## Conclusion

By way of conclusion, let me reiterate that the members of the Service Employees International Union believe that the United States is engulfed in a health care crisis that threatens to leave an increasing number of our citizens without access to health care and to rob the treasury of the funds needed for other public investment. Given this situation, the members of SEIU cannot support untested theories and untried approaches.

Rather than settling for the kind of halfway measures embodied in H.R. 3222, we urge the members of this committee to support the Health Security Act (H.R. 3600), which would provide America's working families with the health security they so desperately need. SEIU is committed to defending the Health Security Act against those who advocate that we move more slowly, make incremental changes, or simply endure our current situation. We are committed to working in coalition with consumers, senior citizens, businesses both large and small, community groups, and progressive providers to fight against those special interest groups defending their financial stake in the status quo.

Once again, I want to thank Chairman Waxman and the other members of the committee for this opportunity to testify. We look forward to working with you to make the vision of "health care that's always there" a reality for America's working families.

Mr. WAXMAN. Dr. Coleman.

# STATEMENT OF WILLIAM H. COLEMAN

Mr. COLEMAN. I am Bill Coleman. I am a rural family physician from Scottsboro, Ala. I am the current President of the American Academy of Family Physicians. It is on behalf of the Academy's 74,000 members that I express sincere appreciation for the opportunity to appear before the subcommittee and provide you with the Academy's view of Representative Jim Cooper's Managed Competition Act of 1993.

Since the mid-1980's the issue of universal health insurance has been of central importance to the Academy. In 1989, we became the first physician organization to develop a plan for universal coverage through the public-private system. Our plan is built on the current model of employer-based insurance. Our plan, Rx for Health: The Family Physicians' Access Plan, calls for universal access to a comprehensive set of benefits that stress primary and preventive care. It calls for everyone to have a personal physician in one of the generalist specialties, family medicine, internal medicine or general pediatrics.

Rx for Health includes specific methods for moving to a physician work force that is balanced between generalist and specialist. It also calls for medical liability reforms and tough cost-containment.

My specific comments on the Cooper bill begin with concern about its provisions regarding universal coverage. While the Cooper plan provides universal access to health care insurance through tax incentives, it does not guarantee universal coverage. No one would be required to buy health insurance under the plan, and employers would not be required to pay for it. The difference between access to health care and actual insurance coverage is critical to guaranteeing universal health care.

Second, comprehensive benefits are not spelled out in the Cooper legislation. The Academy has long supported an explicit, comprehensive benefits package. In Rx for Health, the package covers virtually all medical services. Access to these services is limited only by patient coinsurance and a deductible. Prenatal care, well-baby, well-child care services and childhood immunizations require no patient cost-sharing or deductible. Covering medical services up front, we believe will save money in the long term.

Third, we are pleased that the Cooper plan recognizes the importance of the generalist positions. We support provisions in the bill that increase payments to primary care residents and capping funding to residency programs at 4 years. We also support the Health Care Standards Commission in the plan that sets up a process to allocate the number of entry positions into medical residency programs.

Unfortunately, the Cooper plan does not require a 50/50 split between generalist and subspecialist physicians. The physicians work force goals must meet the health care needs of our population, and we need more generalists and fewer subspecialists. Changing the present work force is a structural change that is fundamental to achieving real cost-containment and universal coverage.

Fourth, the Academy strongly supports enforceable cost-containment by using a global budget. The Academy supports a reliance

on market forces in the Cooper bill. However, should the market work imperfectly, there is no default mechanism. By contrast, both Rx for Health and the Clinton plan specifically include backup provisions, such as a global budget.

We cannot guarantee universal health insurance coverage without reining in health costs. Both the Cooper plan and Rx for Health contain individual reforms to control costs. Administrative and liability reforms are good examples. While these reforms are important, we do not believe real cost containments can be achieved without a mechanism that spans the entire health care system.

Finally, the Academy is extremely concerned about the impact that the professional liability situation is having on patient care in the United States. We strongly support the provisions in the Cooper bill that address the malpractice concerns. This includes the bill's \$250,000 limit on noneconomic damages, reduced statutes of limitation, and alternative dispute resolution systems and periodic payments for awards.

Malpractice concerns contribute to the growth of health care costs through excessive premiums and awards. Fears of malpractice also lead to practice of defensive medicine. But most importantly, malpractice affects the access of patients to needed health care services and particularly in rural areas.

The Academy supports many provisions found in the Cooper plan. We also believe aspects of the plan could be improved. Nevertheless, we look forward to working with both the administration and Representative Cooper to write a health care bill by the end of this Congress.

Thank you, Mr. Chairman, for this opportunity, and I am ready to answer questions.

Mr. WAXMAN. Thank you very much, Mr. Coleman.

[Testimony resumes on p. 153.]

[The prepared statement of Mr. Coleman follows:]



STATEMENT OF  
AMERICAN ACADEMY OF FAMILY PHYSICIANS

Mr. Chairman, my name is William H. Coleman, M.D., Ph.D. I am a rural family physician from Scottsboro, Alabama, and it is my privilege to serve as the current president of the American Academy of Family Physicians. It is on behalf of the Academy's 74,000 members that I express sincere appreciation for the opportunity to appear before the subcommittee and provide you with the Academy's views of Representative Jim Cooper's *Managed Competition Act of 1993*.

**Background**

Since the mid-1980s the issue of universal health insurance coverage has been of central importance to the Academy. At that time, the primary impetus for national concern was the growing number of uninsured people and their inability to access appropriate care. Studies documented what family physicians have long known: people who delay seeking medical care have higher morbidity and mortality and are more costly to treat. As the percentage of the gross domestic product spent on health care in this country has escalated, national attention on the problem of access has shifted to an equivalent concern about cost. The American Academy of Family Physicians shares these dual concerns.

Responding to our membership's concerns, in 1989 the Academy became the first physician organization to develop a plan for universal access through a public-private effort, building on the current model of employer-based insurance. In April 1992, the Academy released its revised and expanded plan for health reform, *Rx for Health: The Family Physicians' Access Plan*.

**Rx for Health**

*Rx for Health* calls for universal access to a comprehensive set of benefits that emphasize primary and preventive care. It builds upon the present employer-based system and requires all employers, including small businesses, to provide insurance to their employees and dependent family members. Employers pay a specific portion of the premium. Employee cost sharing varies according to income.

Better management of patient care is emphasized in *Rx for Health*. A key element of the Academy's plan calls for each person to have a personal physician in one of the generalist specialties (family practice, general internal medicine or general pediatrics). Increased cost sharing is incurred if an individual seeks non-emergency subspecialty care without referral from the personal physician. *Rx for Health* includes specific strategies for moving toward a physician supply that is balanced between generalists and specialists.

Furthermore, the plan calls for improved quality utilizing practice parameters and malpractice reforms, including caps on non-economic damages. And, to address spiraling health care costs, it includes stringent cost-containment provisions. A national health board is established and has the authority to set and enforce a global budget. Enforcement is targeted specifically to those segments of the health care system responsible for inappropriate spending increases.

*Rx for Health* has much in common with President Clinton's plan. However, we find much to support in Representative Cooper's plan, as well. Following is a brief analysis of the Clinton

plan and the Academy's view of the Cooper proposal.

### **The Clinton Plan**

Based on our review of the *Health Security Act*, the Academy supports the principles and many of the strategies espoused in the Administration's health reform proposal. The plan provides a positive framework for considering the many complex issues entailed in health system reform and is a good starting point for revision. Academy members are particularly pleased with the commitment of the President to universal access to a set of comprehensive benefits that include preventive services and prescription drugs and that provide a good start on mental health coverage. As deliberations on reform continue, these elements must not be compromised. Everyone in the United States must have access to comprehensive, affordable, high-quality health care services.

### **The Cooper Plan**

The Cooper plan contains several provisions that are supported by the Academy, as well as provisions we believe could be improved. We look forward to working with both the Administration and Representative Cooper to craft legislation that provides health care insurance to all our citizens. In that spirit, we have made the following specific comments on his plan below.

#### Universal Coverage

The Academy's primary concern with the Cooper plan is its provisions relating to universal



coverage. While we are aware of Representative Cooper's sincere desire to provide health insurance to all Americans, in our view, the proposal falls short in this area.

With the release of *Rx for Health*, the Academy established its firm support for universal coverage. While the Cooper plan provides universal *access* to health care insurance through incentives in the tax code, it does not provide universal *coverage*; individuals would not be required to purchase health insurance and employers would not be required to pay for it. In our view, that is a critical difference.

It has long been the position of the Academy that the issue of universal access to affordable, appropriate health care can best be addressed through a system that is based primarily in the private sector. However, this system must also include a public sector insurance component for people not otherwise covered, and it must include significant structural and financial reforms to promote the delivery of appropriate, cost effective health care services. Universal health care coverage will significantly reduce cost shifting due to a heavy burden of uncompensated care, thereby achieving savings for sectors of the economy now bearing these costs.

#### Comprehensive benefits

While the Cooper plan establishes a health care standards commission to recommend a uniform set of benefits to Congress, the benefits are not clearly stated in the legislation. However, "medically appropriate" and preventive services would be included. No cost sharing would be required for preventive services. Individuals would be permitted to purchase supplemental

insurance.

The Academy has long-supported an *explicit* comprehensive benefits package. In *Rx for Health*, the Academy defines a basic benefits package that covers virtually all medical services. With the exception of prenatal care, well baby, well child services and childhood immunizations, which require no patient cost-sharing or deductible, access to other services is limited only by a required patient coinsurance and/or deductible. In our view, initially covering medical services will save money in the long term. The comprehensive benefits package is buttressed by a requirement to see initially a generalist physician, as noted above, to further ensure that patients receive comprehensive, cost-effective care.

#### Physician Workforce

The Cooper plan recognizes the need to support the availability of primary care. We view this as a structural change of fundamental importance to achieving real cost-containment and universal coverage. While much has been said in recent years about the shortage of generalist physicians (family physicians, general internists and general pediatricians) the rhetoric is often unmatched with action.

We are particularly pleased that the Cooper plan focuses attention on the importance of generalist physicians. Under the legislation, payments to residency programs would be based on a per-resident amount; primary care residents would be weighted at 175 percent of the amount compared to 150 percent for non-primary care residents. Payments to residents would

be capped at four years; money is also included for physician retraining. Unfortunately, the plan does not require a 50/50 split between generalist and subspecialist physicians.

The health care standards commission in the Cooper plan would establish a process to allocate the number of entry positions into medical residency programs based on the number of necessary health care professionals. The total number could not exceed 110 percent of the number of U.S. medical graduates who completed undergraduate medical education in the previous year. The commission would work with health plans and medical organizations to determine the quality, geographic distribution and outpatient setting opportunities for residency programs. The plan establishes a national medical education fund, which would provide money to approved residency programs.

Physician workforce goals must reflect the health care needs of the population. Correcting the problems of specialty imbalance in the system will require significant changes in current federal policies and aggressive interventions. These efforts are controversial as they challenge the status quo, but they are essential if we are to achieve universal access to comprehensive health benefits.

#### Cost Containment

The Academy strongly supports enforceable health care cost containment though the application of a global budget. We took and continue to adhere to this position for two main reasons.



First, ensuring universal health insurance coverage cannot be achieved without reining-in health care costs. If we are to be serious in our commitment to universal coverage, then we must be absolutely serious in our commitment to contain runaway health care costs. Any proposal to provide universal coverage that does not contain enforceable cost-containment is simply not credible.

In the Cooper plan, cost containment is dependent on market forces, specifically 1) price competition among plans, and 2) whether tax benefits in the plan are sufficient to encourage employers and individuals to purchase the lowest cost health plans. While we support the reliance on market forces in the legislation, we do not support its lack of a default mechanism should the market work imperfectly. By contrast, both *Rx for Health* and the Clinton plan specifically include backup provisions, i.e., a global budget mechanism. In the Cooper plan, no national health budgets or other price controls are permitted.

#### *Cost containment in Rx for Health*

In developing *Rx for Health*, we searched for the best mechanisms for achieving real cost-containment. Our strategy, like many other proposals, is multifaceted. We have proposed various administrative simplifications, professional liability reforms, expansions in primary and preventive care, and structural reforms designed to improve the management of patient care. As illustrated above, many of these provisions are contained in the Cooper plan.

However, as important as each of these individual reforms might be, we do not believe real cost-

containment can be achieved without a mechanism that over-arches the entire health care system. When we looked at other developed countries, it was readily apparent that the only consistently successful mechanism for controlling health care expenditures is global budgeting. It may not be that global budgeting is the only mechanism that can control costs, but it the only one that we found to have a documented record of success.

#### *Waste in the Current Health Care System*

The second reason for our support of universal coverage and enforceable health care cost containment relates to the amount of waste in our current health care system. You have seen the studies. The subcommittee should be aware of evidence that twenty to thirty percent of medical procedures may be unnecessary, and you have seen the data showing that the United States spends thirty to fifty percent more of its gross domestic product on health care than any other developed country without even achieving universal coverage.

The cost-containment strategies proposed in *Rx for Health* and in the *Health Security Act* would force a thoughtful consideration of how health care services are delivered. These proposals stand in sharp contrast to the current situation in which we find ourselves, a situation devoid of any meaningful incentives for cost-containment and one in which, by default, health care resources are too often rationed on the basis of the ability to pay. Within the current health care debate, the specter of rationing is often raised in the context of global budgeting. We think this a misuse of the term. With universal access and an explicit global budget, it becomes necessary to carefully define need, appropriateness, and cost-effectiveness in rational and defensible terms.

In the absence of a budget, there is no accountability for allocation decisions, and too often services are rationed in the cruelest way imaginable, on the basis of the ability to pay. We urge you to carefully assess any assertions that one solution or another will lead to rationing. The question needs to be asked, "Compared to what?"

### Malpractice Reform

The Academy is extremely concerned about the impact that the professional liability situation is having on patient care in the U.S. Concerns about malpractice contribute to the growth in health care costs directly through excessive premiums, awards, and administrative payments, indirectly through the induced practice of defensive medicine, and also affect access of patients to needed health care services.

According to a 1988 *Medical Economics* study, 62 percent of family physicians gave up obstetrics between 1982 and 1988. A recent report from the Institute of Medicine states that many rural providers have given up OB services, due, in large part, to the high cost of malpractice insurance and fear of lawsuits. A recent study, *The North Carolina Obstetrics Access and Professional Liability Study: A Rural-Urban Analysis*, concluded that 46% of rural physicians compared to 16.7% urban physicians, decreased their obstetric services due to fear of a malpractice lawsuit.

The tendency of family physician to limit their practices because of the cost of insurance premiums has important implications for health care, especially in rural areas. Family



physicians who include obstetrics in their practices in many areas of the country are providing necessary health care that cannot be offered by other specialists.

The Academy strongly supports the provisions in the Cooper bill that address malpractice concerns, including the bill's \$250,000 limit on noneconomic damages, reduced statutes of limitation, alternative dispute resolution system and periodic payments for awards.

#### Health Research Initiatives

The Academy is gratified that the Cooper bill allocates 15 percent of Agency for Health Care Policy and Research (AHCPR) funding for research, demonstration projects and training to primary care.

For the past thirty years, over 95 percent of all medical conditions have been evaluated and treated outside of hospitals. However, the traditional focus of medical education and research has been on medical problems in referred and hospitalized patients. Thus, the training of physicians and the research agenda have focused almost exclusively on inpatient rather than outpatient evaluation and treatment.

Family practice and primary care research relates to better assisting the generalist physician in diagnosis and treatment of the undifferentiated patient population treated in the ambulatory care setting. The 15 percent allocation should initiate and expand office-based, community-oriented family practice and primary care research.

### Definition of Primary care

As this committee considers issues related to the physician supply we urge that the concept of primary care not be trivialized. A primary care physician (or generalist physician) provides definitive care to the unselected patient at the point of first contact. The *Council on Graduate Medical Education (COGME)* defines primary care as entailing first-contact care of persons with undifferentiated illnesses, comprehensive care that is not disease or organ specific, care that is longitudinal in nature, and care that includes the coordination of other health care services. Such a primary care physician will have been specifically trained to provide primary care services, usually through completion of a residency in family practice, general internal medicine or general pediatrics.

The Cooper plan defines primary care residents as residents enrolled in training programs in family medicine, general internal medicine, general pediatrics, preventive medicine, geriatric medicine or osteopathic general practice, a definition that is broader than current accepted definitions. With the exception of osteopathic general practice, these additional medical specialties do not, in our view, fit the definition of primary care providers.

Although, the contribution of *limited* primary care providers may be important to specific patients, the absence of a full scope of training in primary care and limited practice skills in the full range of primary care services requires that such providers work in consultation with fully trained primary care physicians. Effective systems of primary care will use limited primary care providers as adjuncts to the health care team with primary care physicians taking responsibility

for the total care of each patient.

### Other Concerns

Finally, the Academy is concerned that there are no specific provisions in the Cooper bill to increase reimbursement for primary care physicians, nor are there any provisions relating to either the Clinical Laboratory Improvement Amendments, (CLIA) or the Occupational Safety and Health Administration (OSHA) bloodborne pathogens regulations in the bill.

### *Reimbursement Issues*

The Academy has long-supported a variety of targeted measures to increase Medicare payments for primary care services. The inadequacy of Medicare payment for primary care services constitutes a major disincentive for physicians to select the primary care specialties and to locate in underserved communities.

Under the Medicare fee schedule, payment for office visits are less than the cost to the physician of providing the services. Based on an extrapolation of Medicare payment rates (using the time values and Medicare fees assigned to visit codes), a primary care physician seeing only Medicare patients would be unable to financially support a practice. In addition, because of the Geographic Adjustment Factor, Medicare payment rates in rural areas are generally below average. This circumstance is well-known and is a major disincentive for young physicians to select primary care residency training and to locate in underserved areas. Although the Medicare physician payment reform provisions passed by Congress in 1989 were supposed to

have addressed these issues, problems in the implementation of the fee schedule have all but completely undermined the gains due to primary care physicians.

By its nature, family practice is impacted particularly hard by low Medicare payment rates. This is because family physicians tend to locate their practices in rural areas, because the services provided by family physicians are predominantly office visits, and because a relatively high proportion of family physicians' patients are Medicare beneficiaries. There is, therefore, little opportunity for family physicians to compensate for low Medicare rates.

#### *Physician "Hassles"*

The Clinical Laboratory Improvement Amendments (CLIA) regulations are perhaps the most onerous federal requirements presently imposed on family physicians. The level of regulation, expense and exasperation inflicted on small physician office laboratories has no relationship whatever to improvements in patient care or patient safety.

The impetus for CLIA '88 was in response to quality problems in large reference laboratories performing PAP tests, not physician office laboratories. However, the resulting law subjects office laboratories to the same level of regulation as reference labs. This makes no sense in terms of quality of patient care, and in fact has resulted in reduced access to testing and increased expenses for physicians.

Family physicians routinely perform lab tests to get immediate results to begin appropriate



treatment and monitor care while it is being delivered. The choice, timing, and interpretation of laboratory tests are integral to a physician's clinical decisions regarding subsequent diagnostic and treatment interventions; lab procedures are not a separable aspect of clinical medicine.

The present OSHA bloodborne pathogens regulations are a good example of other federal regulations that serve only to increase the cost of medical care and the administrative burden on physicians without any measurable benefit to patients. The Centers for Disease Control guidelines for universal precautions are straightforward and afford patient and health professional safety in regard to HIV, Hepatitis, B. etc. The OSHA regulations, enforced by intimidating OSHA inspectors, are excessive and threatening to physicians.

### **Conclusion**

The American Academy of Family Physicians appreciates the opportunity to provide observations on the Cooper plan. In our view, the time has come for comprehensive health system reform. This will be challenging for the Congress, the Administration, health care providers, businesses, and patients. Change, even positive change, is always difficult. However, the status quo is no longer acceptable. We look forward to working with you to achieve the positive change that we all seek.

I thank you again for this opportunity to appear before you and would be pleased to answer any questions.

Mr. WAXMAN. Mr. Pollack.

### STATEMENT OF RONALD F. POLLACK

Mr. POLLACK. Dare I say good morning? Mr. Chairman, Mr. Cooper, Mr. Bilirakis, I admire your perseverance.

I come here Mr. Chairman as an admirer of Mr. Cooper, but not exactly an admirer of his bill. As Mr. Cooper knows, we have issued our own critique with respect to the Cooper bill. Much of that is contained in a report that we released on Monday, the salient parts of which are included in my testimony—specifically, the concerns about coverage for everybody, the failure to provide a defined benefit package, the lack of any definition with respect to deductibles, coinsurance, caps on payments and for senior citizens, a lack of any coverage with respect to long-term care and prescription drugs.

I am not going to focus on any of those concerns here today. Rather, I am going to focus on some material frankly that was assisted—developed through the courtesy of the Center for Health Policy Research at George Washington University. I understand it will be included in the record. This is research done for the Henry J. Kaiser Commission on the Future of Medicaid and the Commonwealth Funds. I would like to focus on the out-of-pocket premium burden that would be borne under the Cooper bill for those people who are marginally above the poverty line.

What this—what the preliminary research tries to look at is what would be the premium burden that a family of three would incur to pay for a group health plan that is essentially the average group health plan cost as determined by HCFA. In 1993 dollars, that would be a little over \$3,700, \$3,709.

I might suggest for another plan with different benefits the dollars may be somewhat different. But the central point that is made through these numbers would essentially hold under a plan with different benefits. What the analysis shows is what the burden in premiums would be for people marginally above the poverty line.

I am going to look at two groups, those at 150 percent of poverty and those at 200 percent of poverty. For a three-person household, we are talking about an income level of \$17,835. Under the Clinton plan, which mainly has subsidies through an employer purchase, the amount of money that the family would pay as a premium would be a little under \$769, or 3.9 percent of the family's income. That same household, that same family under the Cooper plan with the subsidy assistance that the Cooper plan provides, would require that same family to pay \$1,855 as a premium. Mind you, I want to emphasize this does not include deductibles, coinsurance or out-of-pocket costs for services that are not covered. So just for the premium alone, that family would be paying 10.4 percent of its income for the premium.

Look at a family at 200 percent of poverty that has an income of \$23,780. That family, under the Clinton plan, would be paying \$742 as a premium, or 3.1 percent of its income. Under the Cooper plan, that family would be paying the entire \$3,709 or 15.6 percent of its income. Again, that 15.6 percent of its income is exclusive of what it would be paying in deductibles, copayments and uncovered services.

Most notable—and I am sure that Congressman Cooper, as he looks at various modifications that he might be interested in supporting, one of the things that I think will need to be taken into account is the adverse impact with respect to work, because the Cooper plan with its subsidies provides a tremendous work disincentive. Let me illustrate that with one set of numbers if I may have that time.

Mr. WAXMAN. We are going to have to take your word for it and have the chart in the record. If you want one sentence more——

Mr. POLLACK. For a family, that jumps from 150 percent of poverty, \$17,835 to \$23,780; that is an increase in income of \$5,945. The increase in premium for that same family under the Cooper plan would be \$1,855; in other words, a tax rate of 31.2 percent. That is over and above what that same family would be losing under the earned income tax credit.

I suggest to you when you look at the subsidies in the Cooper plan you will find that it is a major disincentive for work.

Mr. WAXMAN. Thank you very much, Mr. Pollack.

[Testimony resumes on p. 170.]

[The prepared statement of Mr. Pollack follows:]

## Testimony by

Ronald F. Pollack  
Executive Director

Families USA Foundation

Mr. Chairman and Members of the Subcommittee:

Thank you for inviting me to testify today on the Managed Competition Act of 1993, H.R. 3222 cosponsored by Congressman Jim Cooper and Fred Grandy.

The current crisis in our health system has deprived American families of the peace of mind of knowing that they will always be able to take care of their families' health care needs. The following is an excerpt from a Families USA report entitled "The Human Impact of Health Reform." This report analyzes the three most prominent health reform proposals to determine their impact on ten families experiencing common problems with our current health system.

In today's testimony, I examine two proposals: President Clinton's Health Security Act of 1993; the Managed Competition Act of 1993 sponsored by Representative Jim Cooper (D-Tennessee) and Senator John Breaux (D-Louisiana). As the following analysis shows, the President's health reform plan would provide all of the ten families with the security and peace of mind American families so profoundly lack today. By contrast, under the other proposal, many families would face continued insecurity.



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## PEOPLE WHO WILL LOSE THEIR INSURANCE

*Over two million Americans lose their health insurance each month.<sup>1</sup> Most of these people will lack insurance for less than five months, yet a significant portion will lack insurance for six months or more.<sup>2</sup> During this time, families are at grave financial risk if a member becomes sick or injured.*

*Jerry and Donna Weldon live in Fenton, Missouri with their two young children. Jerry is a plumber and the family is covered through Jerry's union. Every three months, Jerry must work a minimum number of hours in order to qualify for health insurance coverage. Lately, work has been slow and the number of hours required by the union for health insurance will be increasing. The Weldons' eight-year-old son has leukemia and he had a bone marrow transplant this fall. After this procedure, he will need ongoing medical care and prescription drugs. The Weldons are worried that they will lose their insurance in the future because of Jerry's lack of work and the increasing number of required hours for insurance.*

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### CLINTON:

*The Weldons would always have the same comprehensive insurance, regardless of how much work Jerry gets.*

As of 1998, the Clinton bill would guarantee that no American would lose their health insurance, regardless of any changes in health, employment or economic status.

Workers and their families would receive insurance coverage through their employment. Self-employed or unemployed people and their families would purchase coverage directly. Their insurance premiums would be fully tax deductible, instead of only 25 percent deductible as they are now. Discounts would help businesses and families afford their premiums.

Families would choose from a variety of health plans offered by regional health alliances where they live. Employees of firms with more than 5,000 employees could choose from at least three plans offered by their firm.

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### COOPER:

*The Weldons would still have to worry about losing health insurance.*

Under the Cooper bill, all individuals, families and small businesses that choose to purchase health insurance would do so through their local cooperative. Employers would choose to contribute or not contribute to their employees' health insurance premiums, as they do now.

Employees and their families could still lose their health insurance if they lost their job; if they changed jobs; if their employer could no longer afford the premiums; if they retired before age 65; and for a variety of other reasons.

Low-income families and individuals who choose to purchase insurance would be eligible for some financial assistance.

Families and individuals who purchase insurance on their own could deduct from their taxes the premium for the lowest-priced plan.

1. Families USA Foundation, *Losing Health Insurance* (Washington, D.C.: Families USA Foundation, 1993).

2. Katherine Swartz, John Marcotte and Timothy McBride, "Spells Without Health Insurance: The Distribution of Durations When Left-Censored Spells are Included," *Inquiry* vol. 30, (Spring 1993), pp. 77-83.

## CARE UNAVAILABLE FOR MEDICAID BENEFICIARIES

*Low-income Americans face numerous barriers to medical care, even when they are covered by Medicaid, the government's health insurance program for low-income persons. Last year, almost one out of five adults receiving Medicaid were turned away by a hospital or a doctor. Another 20 percent had to go to an emergency room for care because they did not have a regular doctor.<sup>1</sup>*

*In late 1990, Sherri Wilburn of Blount County, Tennessee learned she was pregnant. Although she qualified for Medicaid coverage, neither Sherri nor a social worker at the local health department could find a doctor willing to provide Sherri with prenatal care. Sherri was finally able to schedule her first doctor visit for in her seventh month of pregnancy. Three days before her scheduled appointment to begin prenatal care, Sherri went into labor. Her daughter, Cassandra, suffered brain damage and was hospitalized for months. Cassandra will need special education and ongoing physical therapy. According to one of Cassandra's doctors, Sherri's pregnancy was "complicated by a lack of prenatal care."*

### CLINTON:

*Sherri Wilburn would have her choice of any insurance plan offered in her region with an average premium or lower.*

Under the Clinton bill, all Medicaid beneficiaries would have access to the same plans offered by the regional health alliances as everyone else.

For individuals like Sherri Wilburn who are eligible for Aid to Families with Dependent Children (AFDC) or individuals who receive Supplemental Security Income (SSI), the Medicaid program would make payments to the health alliances and allow beneficiaries to choose among all health plans with premiums equal to or below the average.

Those who receive cash assistance would be responsible for very small copayments. They would continue to receive all mandatory Medicaid benefits and any optional benefits that the state chooses to provide that are not included in the comprehensive benefits package.

Sherri's daughter would be eligible for services through a new federal program for low-income children with special needs.

Persons currently receiving Medicaid, but not receiving cash assistance, would obtain their health insurance through their regional health alliance in the same manner as all other persons. Persons with incomes below 150 percent of poverty would be eligible for some assistance with their premium costs.

### COOPER:

*Sherri Wilburn would be fully subsidized for only the lowest-priced plan offered by her local purchasing cooperative.*

Under the Cooper bill, Medicaid would be replaced. The funds would be used to pay the premium for the lowest-priced plan offered by the local purchasing cooperative for individuals and families with incomes under 100 percent of poverty.

All individuals and families with incomes between 100 and 200 percent of poverty would be eligible for some assistance with the cost of the premium for the lowest-priced plan, based on a sliding scale. All individuals and families with incomes under 200 percent of poverty would be responsible for only a portion of the difference in premiums between the lowest-priced plan and higher-priced plans and for reduced deductibles and copayments.

For those with incomes under 100 percent of poverty, the Cooper bill would cover prescription drugs, hearing aids and eye-glasses and other benefits currently covered by Medicaid and not included in the standard benefits package.

1. Kaiser Family Foundation, "News Release: New Survey Shows Significant Gaps in Medicaid Safety Net" (Menlo Park, CA: Kaiser Family Foundation, March 17, 1993).

## INADEQUATE INSURANCE

*Millions of Americans have inadequate insurance that can leave them with thousands of dollars in medical bills. Such inadequate coverage is most common for families who buy non-group coverage and can only afford or qualify for very limited coverage with high deductibles, high copayments or limitations in benefits. Families USA estimates that 18 million Americans who have insurance are currently spending ten percent or more of their pretax income on out-of-pocket health expenses, excluding expenses for nursing home care, health insurance premiums, Medicare payroll taxes, federal, state and local taxes, and wages lost because of their employers' costs for health insurance.<sup>1</sup> Economists generally consider individuals to be underinsured if they are at risk of spending ten percent or more of their income on out-of-pocket health costs.<sup>2</sup>*

*Susan and David Mast live in Wheaton, Maryland with their three young children. David Mast is a self-employed contractor. In 1992, his income was about \$20,000. He paid \$4,000 to purchase health insurance on his own for his family, but couldn't afford the extra \$4,000 a year maternity coverage would have cost. Even then, the coverage wouldn't have been effective for one year. Their son, Joshua, was born in February 1992. Susan Mast worked two jobs as a proofreader and typesetter and took in babysitting and accounting work to pay off the \$3,300 bill from that birth.*

### CLINTON:

***The Mast family would have a choice of health insurance plans that provide comprehensive benefits, and would save about \$2,000 a year in premium costs.***

The Clinton bill specifies a comprehensive benefit package that would cover a full range of services.

The guaranteed national benefits have no lifetime limitations on coverage and would include: hospital services; emergency services; services of physicians and other health professionals; mental health and substance abuse services; family planning services; pregnancy-related services; hospice care; home health care; extended-care services; ambulance services; outpatient laboratory and diagnostic services; outpatient prescription drugs and biologicals; outpatient rehabilitation services; durable medical equipment, prosthetic and orthotic devices; vision and hearing care; dental services; and health education classes.

A variety of preventive services would be available at no cost. Prescription drug, dental, vision and mental illness services would be more generous than many plans today.

No individual would have to spend more than \$1,500 annually for covered services and no family would have to spend more than \$3,000 annually.

Based on national average premiums, the Mast family would pay approximately \$2,000 for health insurance, and that amount would be fully tax deductible.



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**COOPER:*****Would not guarantee the Mast family comprehensive health benefits.***

The Cooper bill would require all health plans to provide a uniform set of effective benefits, but the bill fails to specify what benefits would be covered within the broad categories of medically appropriate treatments, the full range of effective clinical preventive services and a full range of diagnostic services. The bill does not specify limits on the amount families would have to pay in deductibles and copayments. The bill leaves these decisions to a Health Care Standards Commission and then to the Congress.

The Health Care Standards Commission and the Congress could review annually the uniform set of effective benefits. Thus, benefits could be modified or eliminated every year.

Because their family income is under 200 percent of poverty, the Mast family would be eligible for some assistance to cover the cost of their premium. Given their income, the Masts would have to pay about 19 percent of the premium for the lowest-priced plan, and that amount would be tax deductible.

Since the Cooper bill does not specify a benefit package, it is impossible to determine the amount the Mast family would have to pay for premiums, deductibles, copayments and uncovered services.

1. Families USA Foundation, *Half of Us: Families Priced Out of Health Protection* (Washington, D.C.: Families USA Foundation, 1993).
2. Pamela J. Farley, "Who Are the Underinsured?" *Milbank Memorial Fund Quarterly/Health and Society* vol. 63, no. 63, (1985), pp. 477-501.

## HIGH PRESCRIPTION DRUG COSTS

*An estimated 72 million Americans currently lack health insurance for prescription drugs.<sup>1</sup> Medicare does not cover outpatient prescription drug costs. Elderly persons take more prescriptions, on average, than younger people and have higher drug costs, but less than half (49%) of all elderly Americans have prescription drug coverage.<sup>2</sup> As a result, elderly persons pay almost two-thirds (64%) of their prescription drug costs out of pocket.<sup>3</sup>*

*Iona O'Neill is an 83-year-old resident of Spring Hill, Florida. Iona's income from Social Security is less than \$700 per month. She has no insurance covering prescription drug costs. Iona suffered bladder cancer and now spends \$300 per month on medicine. Her income is too high, however, to qualify for any public assistance with prescription drug costs.*

### CLINTON:

*Iona O'Neill would not have to pay more than \$1,132 a year for prescription drugs.*

As of January 1, 1996 under the Clinton bill, Medicare beneficiaries would be eligible for a new outpatient prescription drug benefit.

After an annual deductible of \$250 per person, Medicare beneficiaries would pay only 20 percent of prescription drug costs up to an annual maximum of \$1,000 (including the deductible). After reaching that maximum, Medicare would cover all drug costs. The benefit would be part of Medicare Part B. Medicare beneficiaries pay Part B premiums that cover 25 percent of Part B costs. The additional Part B premium for the prescription drug benefit would be approximately \$11 per month. After 1996, the deductible and out-of-pocket maximum would increase only for inflation.

Those Medicare beneficiaries who purchase Medigap insurance will also benefit from this new coverage. Three of the ten Medigap policies on the market today have prescription drug coverage. The most generous prescription coverage available through Medigap has a \$250 deductible, 50 percent coinsurance and a \$3,000 maximum annual benefit. Medicare beneficiaries who purchase Medigap insurance with some prescription drug coverage will be able to save money by purchasing policies without this coverage and see their benefits improve.

All Americans under age 65 also would have coverage for prescription drug costs as of 1998 under the Clinton bill. Under the lower cost-sharing plan, individuals and families would pay only \$5.00 per prescription. Under the higher cost-sharing plan, after meeting a \$250 deductible per person, individuals and families would pay only 20 percent of prescription drug costs. If an individual's health costs exceeded \$1,500 or a family's costs exceeded \$3,000 in a year, they would no longer have to make any additional payments for prescription drugs.

### COOPER:

*Iona O'Neill would still have to spend \$3,600 or more a year for prescription drugs.*

The Cooper bill would not expand Medicare coverage to include prescription drugs.

For those under age 65, the Cooper bill does not require coverage of all prescription drug costs. A Health Care Standards Commission would define, and the Congress would approve, a uniform set of effective benefits that provide medically appropriate treatment. As part of the uniform set of effective benefits, the Commission also would specify the level of deductibles and copayments.

The uniform set of benefits could be reviewed annually by the Health Care Standards Commission and the Congress. Thus, benefits could be modified or eliminated every year.

The Cooper bill would cover prescription drugs for persons with incomes under 100 percent of poverty.

1. John Rother, "Statement of the American Association of Retired Persons on the Health Care Crisis in America: A Growing Threat to Economic Security," Testimony before the Joint Economic Committee, U.S. Congress (Washington, D.C.: AARP, September 15, 1993).

2. American Association of Retired Persons Public Policy Institute, "Older Americans and Prescription Drugs: Utilization, Expenditures and Coverage," *Issue Brief Number Nine* (Washington, D.C.: AARP, September 1991).

3. Families USA Foundation, *Prescription Costs: America's Other Drug Crisis* (Washington, D.C.: Families USA Foundation, 1992).

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## EARLY RETIREES LOSING HEALTH BENEFITS

*One-third (32%) of all retirees who have health insurance coverage through their former employers are under age 65.<sup>1</sup> In light of skyrocketing health care costs and new accounting rules requiring employers to report this liability, companies are cutting health benefits for current and future retirees. A recent major survey of larger corporations found that 12 percent of companies responding have eliminated or plan to eliminate all retiree health benefits. Another 56 percent have reduced or plan to reduce health benefits covered.<sup>2</sup>*

*Kazimer "Casey" Patelski and his wife Bonnie live in Costa Mesa, California. Casey was a design engineer for McDonnell Douglas for 28 years. He helped design various aircraft, missiles, satellites and the Skylab Space Station. Casey, who suffered from polio as a young man, turned down numerous job offers from other companies over the years because of the generous retirement benefits, including health insurance, promised by McDonnell Douglas. When Casey retired at age 63, he was assured that he and Bonnie would have health insurance coverage for the rest of their lives. A year later, McDonnell Douglas announced that it was eliminating health insurance benefits for all retirees. Current retirees, like the Patelskis, were allowed to purchase health insurance coverage with their pension funds.*

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### CLINTON:

***The federal government would pay 80 percent of the Patelskis' health insurance premiums until Mr. Patelski was eligible for Medicare.***

The Clinton bill would provide early retirees and their families with guaranteed health coverage. Under this bill, the federal government would pay 80 percent of premiums for retirees between the ages of 55 and 65. For retirees whose previous employers currently pay retiree health costs, their employers would now pay the retirees' share of premiums (20 percent).

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### COOPER:

***The Patelskis would still have to pay 100 percent of their health insurance premiums.***

The Cooper bill would provide no federal assistance for early retirees who are not yet eligible for Medicare, or their families.

If the Patelskis choose to buy insurance, under this bill they would buy that insurance through their local purchasing cooperative.

Their premiums would probably be less than if they had to buy insurance on their own, but they could pay higher premiums than others in the purchasing cooperative because of their age.

1. Steven DiCarlo, Jon Gabel, Gregory de Lissovoy and Judith Kasper, *Research Bulletin: Facing Up to Postretirement Health Benefits* (Washington, D.C.: Health Insurance Association of America, 1989).

2. Hewitt Associates, *FASB Retiree Health Accounting* (Lincolnshire, IL: Hewitt Associates, October 1993).

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**JOB LOCK**

*American families with a member who has a chronic health condition can easily find themselves in the position of being unable to change jobs because the family is dependent on the health insurance obtained through one family member's job. One in five (19%) workers report that they or a family member are locked in their jobs because new work offers limited or no health insurance.<sup>1</sup>*

*Melanie and Randy Wood live in Houston, Texas with their three children. After her third child was born, Melanie intended to leave her job to become a full-time mother. At the time, the family had health insurance coverage through Melanie's job. Jordan, now ten, was born with Sturge-Weber syndrome, a congenital neurological disorder. Jordan also has hydrocephalus and needs a shunt to drain excess fluid from his brain. Melanie started calling insurance companies immediately after Jordan's birth and found that Jordan was uninsurable. Since Randy is self-employed, Melanie was forced to return to work in order to keep health insurance for her family.*

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**CLINTON:**

*Melanie Wood could become a full-time mother and the Wood family would have a choice of health insurance plans for the same premium as everyone else, approximately \$2,000 a year.*

The Clinton bill would eliminate job lock because it guarantees all Americans affordable, comprehensive health coverage.

As of 1998, all employers would contribute 80 percent of average premium costs for health insurance for workers and their families, or more if they choose. As a result, workers would no longer have to choose between jobs that offer health benefits and those that do not.

This insurance would be affordable for small businesses and individuals because low-wage businesses and individuals would be eligible for discounts on premiums; because no business or self-employed individual would have to spend more than 7.9 percent of their payroll on premiums; and because premiums could increase no faster than inflation by the end of the decade.

Immediately upon enactment, the Clinton bill would prohibit insurers from excluding pre-existing conditions for individuals and their families who were insured within the previous 90-day period. For individuals and their families who were not previously insured, insurers could limit coverage for pre-existing conditions for no more than six months. This bill also would require insurers to accept immediately all newly-hired, full-time employees and their families added to groups currently insured. By 1998, this bill would prohibit exclusions for pre-existing conditions under any circumstances.

If Melanie Wood stayed home with her children, the Wood family would purchase their insurance through their regional health alliance and have the same choices as everyone else in the region. They would be eligible for significant discounts on their premiums based on their income. Based on national average premiums, the Wood family would pay approximately \$2,000 a year for comprehensive health insurance. Since Randy Wood is self-employed, that amount would be fully tax deductible.



**COOPER:**

*If Melanie Wood became a full-time mother, the family could purchase insurance and would be eligible for assistance with premium costs, but there is no way of knowing what benefits their premiums would cover and what out-of-pocket expenses they would have. This bill would not eliminate job lock for workers who wish to change from a job with health benefits to a job that does not have health benefits.*

The Cooper bill would not eliminate job lock. Since employer contributions to health insurance would remain voluntary, most employers who do not contribute to health insurance now would not in the future. Thus, workers would still have to choose between jobs that offer health insurance benefits and those that do not.

Individuals and small businesses could purchase insurance through their local purchasing cooperative. The premium cost would be tax deductible, but only up to the cost of the lowest-priced plan. Insurance premiums would vary by age. Any plan that denied coverage to any person, family or group because of one person's health condition would not be tax deductible. For individuals and families who lacked insurance coverage for three months, insurers could limit coverage for six months for any pre-existing condition that appeared in the last three months.

The Cooper bill would not limit the amount insurance premiums could increase each year. It would not provide any discounts to small businesses or self-employed persons, or limit the percentage of payroll they could spend on premiums.

Under this bill, individuals and families with incomes under 100 percent of poverty would be fully subsidized for the cost of the lowest-priced plan and would pay ten percent of the difference between the cost of the lowest-priced and higher-priced plans. Individuals and families with incomes between 100 and 200 percent of poverty would pay a percentage of the premium equal to the percentage their income is above the poverty line for the lowest-priced plan and that same percentage of the difference between the cost of the lowest-priced plan and higher-priced plans.

Since Randy Wood is self-employed, the Woods could purchase insurance through their local purchasing cooperative. Since the Woods' income from Randy's business is 19 percent above the poverty line, the Woods would pay about 19 percent of the premium of the lowest-priced plan. Since Randy Wood is self-employed, this cost would be tax deductible. Since the Cooper bill does not specify a standard benefits package, it is impossible to determine the amount the Woods would have to pay for premiums, deductibles, copayments and uncovered services.

1. Henry J. Kaiser Family Foundation and Louis Harris and Associates.  
 "News Release: One in Five American Families Victim of 'Job Lock.'  
 High Cost and Lack of Insurance Top Reasons" (Menlo Park, CA: Kaiser  
 Family Foundation, October 15, 1993).

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## SMALL BUSINESS OWNERS AND THEIR FAMILIES

*Small business owners, employees and their families encounter great difficulties obtaining affordable health insurance. Small groups generally must pay ten to 40 percent more for health insurance than large groups. Those who would purchase health insurance as individuals or as part of a small business group face another formidable barrier to health coverage—medical underwriting practices. Medical underwriting is the process by which an insurer evaluates the health history and the potential for poor health status, and high claims, for an individual or group. Based on current underwriting practices, approximately 15 percent of all small businesses are ineligible for insurance or eligible only for restricted coverage.<sup>1</sup>*

*Ann and Hubert Maddux live in Corpus Christi, Texas with their four-year-old daughter and infant son. Hubert runs a tackle shop and makes approximately \$25,000 a year. As a small business owner, the best insurance Hubert could get for himself and his family was through his alma mater in 1986. At that time his premiums were \$1,000 a year. After their daughter was born with Downs Syndrome and serious heart defects, the Maddux family's premiums increased to \$17,000 annually. For the last two years, the Madduxes have cut back on their insurance coverage because of the high costs. As of January 1994, the Madduxes pay \$8,520 a year for their insurance. But the policy requires a \$5,000 deductible per person, and payment of half of the first \$10,000 in covered expenses per person. Both children need prescription drugs which the family's insurance does not cover. Medicine for the children costs the family between \$100 and \$200 per month.*

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### CLINTON:

***The Maddux family would save about \$5,700 on health insurance premiums and would have a choice of plans that provide comprehensive benefits. They would have to spend no more than \$3,000 out of pocket annually for their family's health care.***

Under the Clinton bill, most Americans would obtain their insurance through consumer-controlled regional health alliances. This pooling of individuals and businesses would result in lower premiums for those who previously purchased insurance alone as small businesses or individuals. The Maddux family would pay the same premium as all others under age 65 purchasing insurance through the alliance.

Small businesses and individuals would no longer see their premiums skyrocket from year to year. This bill would limit the amount by which insurance companies can raise premiums each year so that, by the end of the decade, premiums would go up no faster than inflation.

Insurers would no longer be able to set the premiums for small businesses on the basis of that group alone. Instead, premiums would be based on health costs for the entire region. Insurers would no longer be able to reject businesses or individuals for any reason.

Small businesses would be eligible for significant federal discounts on premiums. No business would have to spend more than 7.9 percent of its payroll for health insurance costs. Businesses with 75 or fewer employees would pay less if their average wages are \$24,000 or less. The lowest wage small businesses would pay only 3.5 percent of payroll.

Many small business owners would pay less to cover themselves, their families and their employees than they now pay just to cover themselves and their families. Based on national average premiums, the Maddux family, for example, would pay no more than about \$2,800 for health insurance premiums. This amount would be fully tax deductible. The amount the Madduxes currently pay for health insurance would cover the cost for the Maddux family and two additional families under the Clinton bill.

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#### COOPER:

*The amount the Maddux family would pay for premiums and the coverage they would have, including deductibles and copayments, are unknown.*

Under the Cooper bill, the Maddux family and other small businesses and individuals who choose to purchase health insurance would purchase it through their local purchasing cooperative. Since not all small businesses and individuals would choose to purchase insurance, the purchasing cooperatives would not pool as much risk or have as much negotiating power as if all small businesses and individuals had to purchase insurance through the cooperative.

The Maddux family's premiums would differ from others who purchase insurance through the cooperative based on their age. Any plan that denied coverage to any person, family or group because of one person's health condition would not be tax deductible.

This bill does not specify the standard benefits, or the deductibles and copayments.

Small businesses and families could deduct the cost of their health insurance premiums, up to the cost of the lowest-priced plan, and only for the benefits included in the unspecified uniform set of benefits. Small businesses would not receive any discounts on premiums for low-wage workers, nor would there be a cap on the percentage of payroll spent for premiums.

There are no limits on the amount premiums could increase each year.

Since this bill provides no subsidies for small businesses, small business owners and their families would be eligible only for individual subsidies. Families and individuals with incomes under 100 percent of poverty would be fully subsidized for the cost of the lowest-priced plan and would pay ten percent of the difference between the cost of the lowest-priced plan and higher-priced plans. Families and individuals with incomes between 100 percent and 200 percent of poverty would pay the percentage of their income that is above the poverty line for the lowest-priced plan and that same percentage of the difference between the cost of the lowest-priced plan and higher-priced plans.

Since the Maddux family's income is 74 percent above the poverty line, they would pay 74 percent of the cost of the premium for the lowest-priced plan. This amount would be tax deductible.

Since the Cooper bill does not specify a standard benefits package, it is impossible to determine the amount the Maddux family would pay for premiums, deductibles, copayments and uncovered services.

1. Wendy Zellers, Catherine McLaughlin and Kevin Frick, "Small Business Health Insurance: Only The Healthy Need Apply," *Health Affairs* vol. 11, no. 1, (Spring 1992), pp. 174-180.

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## LONG TERM CARE AT HOME

*At any given time, there are an estimated three and one-half million Americans who have great difficulty taking care of themselves. These persons require assistance with three or more of the five most basic activities of daily living—eating, bathing, toileting, dressing and getting out of a bed or chair. The services that they need are largely non-medical in nature and, as a result, options for financial assistance or insurance coverage are very limited. Approximately half of these Americans currently do not receive any paid home care services.<sup>1</sup>*

*Roz and Harold Barkowitz live in North Miami Beach, Florida. Harold is a 72-year-old retired shoemaker who had to give up his business six years ago to care for Roz, age 67, who has multiple sclerosis. They had to sell their house and move into an apartment because Roz could no longer climb the stairs. They get no outside assistance caring for Roz, only someone who comes to clean once a week. Harold's greatest fear is that something will happen to him and he will no longer be able to care for Roz. He currently spends 24 hours a day taking care of her.*

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### CLINTON:

*Mr. and Mrs. Barkowitz would be eligible for services to assist Mr. Barkowitz with caring for his wife. The new program would ensure such care is affordable.*

The Clinton bill establishes a major new program to provide services to individuals with severe disabilities without regard to age. Beginning in 1996, the federal government would provide significant new funds for states to develop plans of care for, and provide services to, persons with severe disabilities.

These persons would be eligible for services that include personal assistance and a wide variety of other services that would help them continue to live in their homes and community. This new program would be fully phased in by the year 2003. Individuals would be responsible for modest copayments based on income.

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### COOPER:

*The Barkowitizes would receive no assistance.*

The Cooper bill does not provide families any new assistance with providing long term care at home.

Under this bill, states would become entirely responsible for long term care expenses currently financed jointly by the federal government and states through the Medicaid program. Thus, fewer services could be available than currently.

1. Data provided by Lewin-VHI, Inc. This estimate includes persons with physical disabilities only. Due to limitations in the data, it does not include persons with cognitive impairments.



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## EMPLOYEES VULNERABLE TO ARBITRARY LIMITS ON BENEFITS

*Approximately 40 percent of all employees and their families are covered by employer health plans that are self-insured.<sup>1</sup> Self-insured companies do not purchase health insurance from a private insurance company. Instead, they pay the cost of their employees' medical care directly. The U.S. Supreme Court recently ruled that self-insured employers may limit or eliminate health insurance benefits at any time, even after an employee or a family member contracts a serious illness.*

*John and Joan Cleveland of St. Louis, Missouri had health insurance through Joan's employer, a company that is self-insured. John was diagnosed with leukemia in September 1990, and he needed a bone marrow transplant. Even though his insurance had a \$500,000 lifetime maximum, the policy capped coverage of organ and tissue transplants at \$75,000. John's transplant cost about \$250,000. John died of complications from his transplant in June 1993.*

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### CLINTON:

*John and Joan Cleveland would have had to pay no more than \$3,000 out of pocket for John's medical care in the year that he had his bone marrow transplant.*

The Clinton bill would prohibit all employers and insurers from imposing caps or exclusions on coverage for specific medical conditions or any lifetime limit on benefits for covered services. The bill would require all businesses, whether they pay for their employees through a regional health alliance or through their own corporate alliance, to provide the comprehensive benefits specified by federal law. John Cleveland's bone marrow transplant would have been covered.

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### COOPER:

*Joan Cleveland's employer could not impose arbitrary limits on the Clevelands' health benefits, but it is impossible to know if John's bone marrow transplant would have been covered. It is impossible to determine the amount the Clevelands would have had to pay out of pocket for John's medical care.*

The Cooper bill would prohibit all employers who provide insurance, either through a purchasing cooperative or on their own, from limiting any benefits in the uniform set of benefits.

The bill, however, does not specify the uniform set of effective benefits within the broad categories of medically appropriate treatments, clinical preventive services and diagnostic services. The bill also does not specify the amount families would have to pay in deductibles and copayments. The uniform set of benefits could include limits on benefits for specific treatments or diseases. The bill leaves these decisions to a Health Care Standards Commission and then to the Congress.

The Health Care Standards Commission and the Congress could review annually the uniform set of benefits. Thus, benefits could be modified or eliminated every year.

1. Cynthia B. Sullivan, Marianne Miller, Roger Feldman and Bryan Dowd, "Employer-Sponsored Health Insurance in 1991," *Health Affairs* vol. 11, no. 4, (Winter 1992), pp. 172-185.

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## EMPLOYERS WITH SKYROCKETING PREMIUMS

*The amount American families and businesses are charged for health care has far outpaced increases in family income and business profits. Today, business spending for health care nearly equals the amount corporations make in after-tax profits. By contrast, in 1980, business health care spending amounted to 41 percent of corporations' after-tax profits.<sup>1</sup> If health care inflation had been held to the same rate of inflation as the rest of the economy from 1980 to 1992, health care costs for businesses today would be one-third less than they are. This difference averages about \$1,000 per worker.<sup>2</sup>*

*Roger Flaherty owns a small company, Floor Covering Resources, in Kensington, Maryland. He has two employees, and they are covered by a small group health insurance plan. Both employees have ongoing health problems. In 1987 Roger paid \$285 a month to cover these employees. In November 1993, his premiums increased to \$885 a month. The business pays the full cost of the insurance. Roger is committed to providing health insurance for his employees, but doesn't know if he can continue to afford it.*

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### CLINTON:

***Mr. Flaherty would see his health insurance premiums for his employees go up no faster than inflation by 1999.***

The Clinton bill would limit the amount by which all insurance companies could raise premiums. By 1999, American families would no longer have to swallow health insurance premium increases that are larger than general inflation. American families would see larger wage increases and more disposable income and businesses would see less of their profits eaten up by health cost increases and have more money to invest and to create new jobs.

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### COOPER:

***Mr. Flaherty and other employers would see their health insurance premiums continue to climb uncontrollably.***

The Cooper bill does not limit the amount health insurance premiums could increase annually. Mr. Flaherty's expenses could continue to increase far faster than inflation. Employers and workers would not be protected from the devastating economic effects of rapidly rising health insurance premiums.

1. Cathy A. Cowan and Patricia A. McDonnell, "Business, Households and Governments — Health Spending 1991," *Health Care Financing Review* vol. 14, no. 3, (Spring 1993), pp. 227-248.

2. Service Employees International Union, *Out of Control, Into Decline: The Devastating 12-Year Impact of Healthcare Costs on Worker Wages, Corporate Profits and Government Budgets* (Washington, D.C.: SEIU, October 1992).

Mr. WAXMAN. I want to thank each of you. You have given us excellent testimony.

Dr. Coleman, your organization, the American Academy of Family Physicians, did you say that your organization had a benefit package that you thought was a reasonable one?

Mr. COLEMAN. Yes, sir. It is Rx for Health. I thought that had been distributed.

Mr. WAXMAN. I am sure it has. Do you have a lot of politicians there making those decisions? Do you think that you are capable of making them without having some—

Mr. COLEMAN. Yes, sir, we do. We have had commissions in our Academy consisting of 12 physicians each; 6 worked on this, and we worked with the—

Mr. WAXMAN. We should, I think, pay attention to the recommendations you have made—this is a better way to phrase this. We should pay attention to the recommendations you have made because we know that they have been designed by people involved in health care and are not going to be responding to political pressures, as my colleague rightfully pointed out sometimes happens when elected officials decide what should or should not be in a plan.

Mr. COLEMAN. I gratefully accept the way you stated that, sir.

Mr. WAXMAN. I hope my friend over there does, too. We went through a lot of these issues but I am concerned about that \$40 billion cut in Medicare that takes in the elderly to subsidize low-income people. In the Clinton proposal, he would take some reductions in increases for Medicare and use it for improving benefits. I am just troubled that the elderly are going to find themselves aggrieved if they suddenly find cuts in their increases to pay for their medical services, for which they get nothing in return and for which they may be worried that they are going to have less access to good care.

I don't know if anybody wants to respond.

Mr. POLLACK. The thing that senior citizens are most concerned about is, they are really worried about home care and long-term care. There is nothing in the Cooper bill that does anything for them there. They are really concerned about the cost of prescription drugs. There is nothing in the Cooper plan that helps them there.

There are two problems. One is, the Cooper plan would cut Medicaid funding which would leave the States in a more difficult position with the commitments they already have on long-term care; and it would exacerbate the differential between what you get with public-financed versus private-financed care, which will make it more difficult to gain access to a doctor and a hospital.

Mr. WAXMAN. You raise a good point, because this morning I learned for the first time—and maybe the authors of the bill did, as well—that they repealed title XIX, which repeals all of Medicaid, including that part of Medicaid which pays for nursing home benefits, presumably leaving it to the States to decide what to do with funding nursing homes or home health care.

Mr. BARNETTE. It is inevitable that if Medicare and Medicaid are reduced that the States will find ways to simply shift those liabilities onto the employers in some way or other. That is inevitable.

Mr. WAXMAN. That is a good point. I hope somebody who called up the members of the Business Roundtable—if they spend more time doing that than threatening the members of their families, we would probably get more attention paid to it.

Thank you very much.

Mr. Cooper.

Mr. COOPER. I appreciate the expert testimony of the panel. I regret that Dr. Coleman wasn't on my panel.

The main questions would be for Mr. Barnette. You have a terrific imbalance, it seems to me, between active employees and health care beneficiaries. Have you calculated how much money the Clinton bill would help you in providing benefits to your retired population and others? How much is it worth to your company to have the Clinton bill?

Mr. BARNETTE. I think we calculated first what the Clinton bill would do for all America in terms of reform that is much needed; whether it is in the form of the Clinton bill or your bill, that is our starting point: What is the overall public interest in terms of health care reform?

Second, in terms of Bethlehem Steel's health care liabilities, yes, there would be some improvements and some reductions in our liabilities because of the gross inefficiencies that exist in the present health care delivery system. Certainly the cost-containment issues are part of this plan, but they will be applicable to many corporations other than Bethlehem.

Third, many of our problems are caused by the ravage—significance of unfair trade that has taken place. We see this as a matter of international competitiveness. Health care reform is vital for our ability to compete in a tough foreign market in which we are now the low-cost, high-quality producer of steel in this country.

We see all those implications.

Mr. COOPER. But as a percent of payroll what are your health care costs today?

Mr. BARNETTE. It depends on the starting point. I think the relevant percentage for purposes of this analysis is, if our health care costs are \$231 million this year—we have a health care beneficiary population of 161,000—our health care costs as a percentage of the active payroll are 24 percent.

We have 22,000 employees. They are supporting 161,000 beneficiaries at a cost of \$231 million. Our individual, per capita health care costs, we have managed very effectively and efficiently on a per capita basis. They are quite reasonable and our health care trend rate is quite reasonable.

Mr. COOPER. I am not saying this is anyone's fault. I just want to understand.

So under the Clinton bill, if the current percent of payroll is 24 percent, that would be lowered to 7.9 percent?

Mr. BARNETTE. We are using a different calculation, I think, for this analysis. I am explaining to you what our costs are and a way of doing that in terms of the Clinton plan, my understanding is, it would be a percentage of payroll cost; and our payroll cost is some \$1 million aggregate payroll cost. We continue to have liabilities for retirees and for other beneficiaries.



Mr. COOPER. I want to help figure out a fair and just way to help folks. I have been told by a number of folks that this could be a windfall to some companies if their percent of payroll costs is well above 7.9 percent and it becomes the law of America that you never have to pay more than 7.9 percent.

Mr. BARNETTE. I would hardly characterize it as a "windfall."

If I may, I would be happy to give you detailed cost judgments on the pending legislation.

Mr. COOPER. That would be helpful. I don't want to keep you from that important Business Roundtable vote coming up here.

Mr. BARNETTE. I intend to be there.

Mr. COOPER [presiding]. I would like to turn the questioning over to my colleague, Mr. Klug.

Mr. KLUG. I want to follow up on what Mr. Cooper just said, Mr. Barnette. To the degree that you and a lot of other major U.S. corporations, especially in the manufacturing sector, have large groups of retirees, you have to provide for; but at the same time, under the President's plan—I have a number of companies in my district who pay much less than 7.9 percent. Under the President's plan, why do we want to penalize companies that are already doing a more efficient job than companies like yours are doing?

Mr. BARNETTE. I don't think we want to penalize any company. Hopefully, that will not be the case.

However, I think the case is responsibly made that many of our major companies have gone through such restructuring, have for many years been substantially overpaying health care expenses. This legislation, I think, will bring health care expenditures under reasonable control. I think that is the benefit.

Mr. KLUG. No argument from me, and I have been involved with Jim and Fred for a year trying to come up with a plan. We see ourselves as part of a solution, although we may disagree which way to get there. I think from an economic perspective, while you and GM and Ford may all prosper under this and see your rates go down substantially, I am going to see medium-sized companies in Wisconsin have their rates go up dramatically. And from a public policy perspective, we now assume liability for early retirees from 55 to 65.

What message does that send to corporations 5 or 6 years from now? Aren't we going to see the numbers swell dramatically, because it is a terrific invitation, if I am a major company, to say, I am going to give this to the government.

Mr. BARNETTE. That is misunderstood. There are many pre-Medicare retirees in just the classification we are talking about, who are not associated with any particular company. Again, the specific demographics of the steel industry certainly do not suggest that it is a windfall for the steel industry.

If we take our numbers today of early retirees, look at the numbers in 1998 and look at the numbers in the year 2001—and that is the transition to phase-in, the so-called "pre-Medicare retiree coverage," the numbers are decreasing very substantially. I think it is a matter of fairness to all early retirees, whether from large companies or otherwise, to have the certainty of medical care.

Mr. KLUG. Mr. Pollack, you indicated earlier support for expanded prescription services for seniors. Does your organization at

the same time think those seniors should be qualified by means-testing for prescription services?

Mr. POLLACK. I don't particularly have any grievance with the notion of tailoring premiums based on income. I think it is a progressive thing to do. I think that it can best be done perhaps by having a sliding scale with respect to out-of-pocket costs that they bear, and deductibles and copayments. So I think that if we made that change and we tailored it based on financial need, I would be very happy to see that.

Mr. KLUG. Would you support other means-testing changes in the Medicare program for seniors to guarantee that we could continue to provide coverage to folks that really need help?

Mr. POLLACK. Families USA has taken the position that the premium financing of the Medicare program under part B is a regressive way of doing it. I think it is ridiculous for somebody at a \$75,000 income to be paying the same premium as somebody making \$25,000. If we could make it more progressive, we would support that.

I might say, however, that in terms of the difficult political elements of achieving that, I think that is best done in the context of a significant reform that includes some of the most crucial benefits that seniors are looking for, like prescription drugs and long-term care. In that context, I think politically it is easier to achieve that kind of tailoring based on income, which I don't think you can achieve outside that context.

Mr. KLUG. I think your instincts are correct. Thank you for your testimony.

Mr. WAXMAN. Thank you, Mr. Klug.

Further questions? Thank you very much for your testimony. We look forward to working with you.

We now resume our hearing on H.R. 3222 and other health care reform legislation. On our first panel this afternoon is the Honorable J. Roy Rowland of Georgia and the Honorable Michael Bilirakis of Florida who will present testimony on their bill, H.R. 3573, the Community Health Improvement Act of 1993.

It is a special pleasure today to have a hearing where we have so many of our colleagues on the subcommittee testifying to us. You have important information to give us as to how to sort through the difficult job of enacting health care reform, doing the best for the American people, making progress to make the system work better for everyone.

We are delighted to have the two of you with us. Your prepared statements, as you have heard me say many times before, will be in the record in full. We would like to ask you to limit the oral presentation to no more than 5 minutes.

Dr. Rowland.

#### STATEMENT OF HON. J. ROY ROWLAND, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Mr. ROWLAND. Thank you very much. I am not so sure how much I like having this shoe on my foot. I will know better how well it fits after I finish this testimony.

Mr. Chairman, thank you for the opportunity to present our views about the consensus proposal and our concept for broadening

access to care, particularly for the medically underserved. It is important to consider all points of view, and the subcommittee should be commended for helping make this possible.

As a family physician, I know from firsthand experience how people are affected by the bewildering range of problems that have plagued the health care system for years.

Our goal is to address every one of these problems and help rebuild a system that provides quality, affordable access to everyone.

As a legislator who has been involved with health care policy on the State and Federal levels, I also know how difficult it is to achieve this. Medicare and Medicaid are examples of how Washington tried to address the problems of the elderly and poor, and expectations were never fulfilled as costs soared far beyond any projections. Many things have been tried since then and the problems only get worse.

Our goal is also to help make sure we do not make the same mistakes again. In my view, we should not implement experimental programs before they have been adequately studied and tested and we should not try to fix parts of the system that are not really broken.

We view our consensus legislation as a beginning. It is an effort to establish the debate on a foundation of agreement rather than on one of divisiveness. From the standpoint of quality, and even perhaps the quantity of reform, we believe we can achieve more this year in an environment of cooperation than we can in the midst of a political and philosophical free-for-all.

It is a plan that can help get the health care reform process moving forward. It is a problem-oriented approach that can help sort out which ideas should be implemented now and which should be studied further. And it can be a substantial basis on which we can enact additional reform.

The reforms included in our consensus proposal, with few exceptions, are also included in virtually every one of the other comprehensive health care plans pending in Congress. The provisions may not be exactly the same in all instances, but they are similar.

Included are:

Insurance portability, so insured workers won't lose their coverage if they change or lose their jobs;

Noncancellability of policies and prohibiting exclusion for pre-existing conditions, to give people the health care security many now lack;

Malpractice liability reform, to reduce so-called "defensive medicine" and create a better system of accountability;

Increased preventive care programs that emphasize primary care, inoculations, and early diagnosis of health problems;

Administrative streamlining, to reduce the costs and hassles of paperwork;

Antitrust reform, to facilitate the consolidation of services and reduce costly duplication;

The consensus legislation is now in the final drafting stage and we expect it to be ready for introduction soon. Some of the details are still being worked out. We are trying to refine and strengthen these reform provisions as much as we can. But, again, they will be similar to those in plans already before you.



We introduced the Community Health Care Improvement Act in November. This plan can potentially provide access to care to every citizen, particularly the Medicaid eligible population and the uninsured and underinsured.

There are features in this plan that we believe also have consensus potential. It is based on community initiative more than Federal control. It does not rely as much on bureaucratic regulation as some other access plans do. It is a system built around community health care centers, which have a proven record of cost-effectiveness.

In Georgia, there are 25 community centers providing a wide range of medical, laboratory and x-ray services for an average cost of just \$190 per patient per year, according to the Georgia Association for Primary Health Care. There are more than 700 of these facilities around the country. If encouraged, many more will emerge.

Our proposal would link community hospitals to these centers, where inpatient and outpatient care would be provided to enrolled patients either free of charge or on an ability-to-pay basis. Although partly financed with Medicaid and other Federal funds, as well as State and local funds, grants from foundations and other sources, it is a system that would enable communities to tailor services to their own needs.

Mr. Chairman, we are concerned about the conflicts that exist in this debate over reform of the health care delivery system. Our purpose is not to compete with other plans, but only to make sure this opportunity to make real progress in health care reform does not slip away.

Thank you for the opportunity to be here this morning.

Mr. WAXMAN. Thank you.

Mr. WAXMAN. Mr. Bilirakis.

#### **STATEMENT OF HON. MICHAEL BILIRAKIS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA**

Mr. BILIRAKIS. Thank you, Mr. Chairman. I have already thanked you and commended you for your open-mindedness and for your willingness to allow all these plans to be presented. I very much appreciate your giving us this opportunity.

My friend and our colleague, Dr. Rowland, has ably outlined the major points of our bill. Of course, he talked about the Community Health Centers bill which has already been introduced, but he also talked about the Health Reform Consensus Act, which is in the process of being drafted and will be introduced some time next week we believe.

Quite simply, Mr. Chairman, we believe it is imperative to begin the process of health reform with the consideration of items where there is broad bipartisan agreement. Our draft bill draws legislative language from the Clinton administration proposal, the plan offered by our colleague, Representative Cooper, the Michel bill, and the Bentsen legislation of 2 or 3 years ago.

We have intentionally violated the copyright in order to draft a bill Henry Clay might find judicious and passable. We believe our bill will provide real relief now to real Americans. Provisions on portability will prevent job-lock, a situation where individuals are



forced to stay with unrewarding employment simply to maintain insurance.

I am certain, too, that each member of this subcommittee has heard horror stories back home of individuals denied coverage due to preexisting conditions.

We all know that preventive care can save scarce resources and improve the quality of life for many individuals. Malpractice reform is also sorely needed as we all have said so many times, and we must eliminate fraud and abuse inherent in our current system.

Our consensus bill addresses these issues in addition to changing the antitrust laws to afford facilities the opportunity to share resources. The point of our legislation, Mr. Chairman, is that people are hurting now. And we can do something to help now. We can act now and correct many identifiable problems with our health care system. However, as you know, no single bill that has been introduced in Congress has received anything close to majority support.

Only 21 percent of House members have signed on to the McDermott legislation. Only 23 percent have cosponsored the Clinton bill. Only 13 percent support the Cooper bill, 1 percent the Thomas bill, 32 percent the Michel bill, and 4 percent the Stearns bill.

In this fractious situation we must seek common ground. We must seek consensus and that is precisely what our bill draft will do. Significantly, the bill provides a ready majority for both committee and Floor action. As of January the 26th, 297 Members of the House supported at least one of three bills that we used in drafting our consensus legislation. Many members also support multiple bills, as we know, and 101 of our colleagues agree with the basic principles of our approach.

Our bill offers a harmonic convergence among the din of Harry and Louise, the newspaper ads of the health care reform project and the rumblings of Rush Limbaugh. It offers a chance to begin the debate from a point of common reference. We also believe that the bill does not represent a final product, and I do want to emphasize that, Mr. Chairman.

There is no intent that it represents a final product. Instead, we view our bill as a starting point for reform of the Nation's health care system, a basic foundation on which to build. This, we believe, is crucial to the legislative process of health reform. To those who are concerned about universal access, our bill offers a platform for amendment. To those members who want a vehicle for cost containment, nothing in our bill would prohibit the imposition of further cost controls.

Our fundamental position, however, is that these provisions should be added to the basic consensus bill by affirmative vote under majority rule. We should use a consensus bill to first fix what we know is broken, and then debate and vote on amendments addressing the broader questions of access and cost containment. We believe that the Democratic process works best when it is a process of addition, rather than subtraction.

Members should be allowed to cast their votes yea or nay on the fundamental elements of providing access and controlling costs. We believe we should build a health care reform house from the ground

up with each plan standing on its own merit. Conversely, if we start from a committee print based on the Clinton health care proposal, Mr. Chairman, the bill text will land in our committee much like the farmhouse in the Wizard of Oz. We will hear a thud and then most likely a whimper.

Under this process, we will be asked to strip away objectionable elements under the threat of a veto. We will start with a completed house, and then be asked to rebuild it without breaking any windows or scratching the paint. And, Mr. Chairman, you yourself have said that the veto, and I quote from a recent Washington Post article, "holds the prospect for Republicans and some nervous Democrats that they will be held responsible if health care fails. And that is a tough label for those people to have when they go back home to face the voters in November," end quote. So, Mr. Chairman, let us instead start from a position of true bipartisanship and let us stray away from abject politicization of the legislative process.

This health care debate should and must be about intelligent reform, and not about, as you have said, November elections. And in terms of simple fairness, we ask that whatever proposal becomes the markup vehicle, that the Chair continue, and I know you will, its long-standing policy of allowing any member of the committee to offer any amendment or substitute to the bill which falls within our subcommittee's jurisdiction. And at the risk of disagreeing with our full committee Chair, at considerable risk, I might add, although he isn't here, so maybe the risk is lessened somewhat, I must also individually state that I believe we should not labor under artificial deadlines to the detriment of the process.

Our prime obligation is to thoroughly consider the health reform bill in an orderly fashion. We know, Mr. Chairman, that the administration has missed deadline after deadline on health care, and now we are told we have only a few weeks to act. Something is wrong with this picture. We must act on health reform. We must act in the sober light of day with our full wits about us.

In conclusion, Mr. Chairman, I know I speak for both of us and for many others. We are willing to work with you throughout the coming weeks, but we would hope that you also give full consideration to a bottom up process of amending a core bill, whether it be ours or another subcommittee print.

In the interest of time, Mr. Chairman, I will finish up by saying that again we need to face the facts. With only 21 percent of House members supporting McDermott, only 23 percent the Clinton bill, only 13 percent the Cooper bill, 1 percent the Thomas bill, 32 percent the Michel bill and 4 percent the Stearns bill, we cannot take an all-or-nothing approach with regard to health care reform.

We are probably never going to get what we really need to do done that way. And so we drafted our bill in an attempt to define a common position among the competing proposals that have been introduced.

Mr. Chairman, we can do it if we truly want to.

Mr. WAXMAN. Thank you very much. Both of you, I want to commend both of you for your testimony. And, Mr. Bilirakis, I took those statements you made to me as very constructive ones, and to show my friendship, I am not going to show the transcript of this

hearing to Mr. Dingell, so he won't even know what you said about him.

The two of you have offered a very constructive bill, and I want to commend you, particularly on the community and migrant health centers program. I think they are tremendously important, no matter what we do in health care reform. And you have given us a number of the ideas for which there is a consensus.

Now, I think the job of this committee is to see is there more that we can do, is there broader consensus we can develop. And that is what we have got to do together. So I appreciate your testimony.

Mr. Cooper, questions?

Mr. COOPER. Thank you, Mr. Chairman. I appreciate the friendship and expertise of my colleagues. I have enjoyed working with both of you on a number of issues. The consensus proposal is a very novel committee procedure that I hadn't thought of before, and I am looking for any idea to make sure that we can break the gridlock on health reform.

It is awfully hard to overcome pride of authorship and things like that, even when folks say they have no pride of authorship, that is kind of when you know that they do. So I look forward to seeing the draft of the bill when test released and see exactly what sort of combination of those bills that it actually is.

I have particular regard for my friend and colleague, Dr. Rowland, because, as you know, there are so few health professionals even in politics, much less in this body, much less on this committee. And as we debate these crucial areas, it worries me deeply that any politician who blocks access to a physician or health provider by a patient is going to be a dead politician.

You know, the most intimate, personal and urgent concern that any of us ever has is when we are sick, or a loved one is sick. And the health professions have a special expertise that we rely on regularly. That is such an ironic situation, when our own doctor is probably our most trusted advisor, and yet somehow, according to the polls, doctors are not very popular. It is kind of like Congress, people like their own Congressmen, but don't like Congress.

Mr. ROWLAND. I have a double click.

Mr. COOPER. You do. Have you ever sold any used cars?

So as we work through these things, whether it is beefing up community and migrant health clinics, which certainly needs to be done, and we have about \$100 million, I believe, in our bill to try to do that, but I want to work with you to make sure that I understand exactly how we need to strengthen those programs, whether as an alternative to my bill or as a supplement. Also I want to work with you to understand the best way to draw up this basic benefits package.

There has been a lot of discussion on today. Because despite the high regard I hold my colleagues in, I get deeply worried when I think that we would be specifying the details of a package. Perhaps we would choose wisely, perhaps not. Even if we did write it in statute and it was perfect, a new medical discovery could happen during the recess and we would have to reconvene Congress to adjust the package. I just worry that if we do it, it won't be basic, it won't be scientific, and it won't be flexible enough to meet human



needs. But I look forward to working with you and, Mike, and others to make sure that we can come to a good solution to these troubling problems. And I am just delighted that we will have your expertise not just as general in Congress, but here on the committee as we wrestle with these tough problems.

Mr. ROWLAND. I really appreciate your kind words and those of the chairman as well, and certainly look forward to working with you as well. I will have to tell you that we have plagiarized a little bit of your legislation—

Mr. COOPER. Good.

Mr. ROWLAND [continuing]. Trying to put our consensus bill together, as was pointed out by my good friend and colleague, Mike Bilirakis. We have taken a lot from other bills and while it may have made some little changes in it, but for the most part very similar to legislation that is already out there. So we certainly don't have any pride of authorship of much of the language in the legislation that we will be introducing as consensus legislation. I do appreciate very much your kind remarks.

Mr. WAXMAN. Thank you, Mr. Cooper.

Mr. Hall?

Mr. HALL. Mr. Chairman, thank you. I have the opportunity to make a comment when I didn't have to sit here and listen to the testimony. I join the gentleman from Tennessee in saying that I am proud that there is a doctor in the House. And also pleased that there is a patient in the House, because Mike has been a patient. And a lot of us have had his health as a great concern, because he is a very dear friend. And that is how—that is why this whole thrust is so important to so many people out there that mean a lot to us.

And there are those out there that can't get insurance today. And I really think the country should feel good that while I am bragging on people, that we have a chairman that totally understands the health thrust and cares about people. And though we haven't always agreed on the avenue to get there, his word has always been good to me and I have always had to run with what I wanted to run with. So I think we have a good platform here to spring from, and we have a little bit of difference of opinion, but I think all of us certainly want to get there.

And I want to add my voice to the support of the work that both of you have done. We have had support for insurance reform, standardization of benefits and billing, malpractice and tort reform, and we should have passed these reforms when Secretary Bentsen first recommended them. These ought to already be on the books, but it is not too late and I think Dr. Rowland, you have had some good ideas on how to expand, enhance and promote our community health centers.

I am fortunate to have a very excellent one in Greenville, Tex., right in the heart of my district there, and I believe health access and delivery can be greatly improved by increasing the number of community-based clinics that serve neighborhoods and entire communities. It is working very well there.

I understood that our President was in favor of going ahead with these reforms at one time, and in the course of several days and nights, he was changed, and that the First Lady really didn't want



to go ahead with these reforms because she thought it would take from her overall program. And it seems to me it would make a lot of sense to go on and put them on the books now. It would give us a year, at least a year's head start on saving some money that can be applied to whatever type bill that we do pass. But I thank you for the hard work you all have put into it, and, suggest that we look forward to working with you as we move along.

I yield back my time.

Mr. ROWLAND. If I may, Mr. Chairman, I really appreciate the kind remarks, and I am glad you came in when you did, Mr. Hall, because I am really pleased to hear you say what you said. And I look forward to working with you. And I agree with what you said about the chairman.

While we may not always agree on a specific item, there has never been any doubt in my mind that our goal was the same. We were always looking for a way to provide the best quality care for everyone that was affordable for them. I appreciate that. Thank you very much.

Mr. WAXMAN. Thank you. Thank you both very much for your testimony. We are certainly going to look forward to working with you.

We now have the opportunity to hear from another one of our colleagues on the Energy and Commerce Committee, the Honorable Cliff Stearns of Florida. He is a sponsor of H.R. 3698, the Consumer Choice Health Security Act of 1993, but presumably would be changed to 1994.

Mr. Stearns, we are pleased to have you with us. Your prepared statement will be in the record, without objection, in its entirety. We would like to ask you, if you would, to try to keep the oral presentation to 5 minutes.

#### STATEMENT OF HON. CLIFF STEARNS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Mr. STEARNS. Thank you, Mr. Chairman. Appreciate the opportunity that you have extended to me to testify here on your committee. There is a portion of this I would like to read and put—even though you have been kind enough to put it in the record. I would like to read a portion of this.

As you mention, it is H.R. 3689. On the Senate side, Senator Nickles has offered the same companion bill, it is S. 1743. We dropped it last year so it has the title of the Consumer Choice Health Security Act of 1993. Senator Nickles was to be here today. Unfortunately, he had a conflict of schedule and he couldn't be.

As members of this committee are aware, the issue of health care reform has been in the forefront of our citizens' concern, and rightly so. The President's State of the Union Address, we all heard him say that he would not sign a bill into law that did not guarantee universal coverage. H.R. 3698 does that and more.

As such, I believe that it merits full consideration by the Congress before a final bill is brought to the House Floor for a vote. I would like to quote, Mr. Chairman, the President, from his State of the Union remarks, when he said, quote, "The American people provide those of us in government service with terrific health care benefits at reasonable cost. We have health care that is always

there. I think we need to give every hard working taxpaying American the same health care security, that they have already given us here in Washington."

Mr. Chairman, over 40 of my colleagues and yours here in the House and Senate agree with that statement. That is why we have introduced this bill, the Consumer Choice Health Security Act of 1993.

Now, as the title indicates, this legislation seeks to provide quality, necessary medical care to all Americans through the oldest proven mechanism, the free market. Furthermore, this legislation is patterned after the Federal Employee Health Benefit Program that has been in existence for over 30 years, and it has held down its costs while providing quality health care.

As you know, Mr. Chairman, all Members of Congress our staff, the President, the Vice President, the Cabinets, the Supreme Court Justices, and some 10 million employees, retirees and dependents, are enrolled in this plan. The program is unique in that it is explicitly based upon the free market principles of consumer choice and market competition.

Unlike our constituents, we have the luxury of being able to pick and choose from over 30 different health care plans, be it a traditional, HMO, PPO, or a union-sponsored plan like the postal workers. Unlike the rest of America, we get to make a personal choice, compare the prices, and level of benefits of each plan. We then make a decision based upon our budget, our needs, and our bottom line, not some corporation's bottom line.

While the FEHBP model is not perfect, with the modifications that have been added in our bill, this plan can be expanded to cover all Americans. Combined with an individual mandate, rather than an employer mandate, that is explicitly written into this bill, the President's goal of universal coverage is met. The Government program is a sound program with good benefits and while the level of benefits has increased over the years, costs for these plans have been effectively kept down. Not with price controls, mind you, but with competition.

On September 14, 1993, Jim King, the Director of Office of Personnel Management, stated, and I quote, "Our enrollees continue to gain from the competition and management care that form the backbone of the Federal Employee Benefits Program."

Mr. Chairman, this is evidenced by the fact that the price of premiums for Federal employees that they have to pay in 1994 are only 3 percent higher than the prices they paid in 1993. In short, the market forces have worked for the FEHBP program. There is no reason why these same principles cannot be worked for the American people.

Most Americans are kept out of the picture when it comes to purchasing health insurance because it is usually purchased by their employer. Doctors and hospitals rarely discuss bills or fees required for delivery of care and rely on third party reimbursement.

Consumers are shielded from the true cost of health care and as such there is no incentive for all parties involved to control costs. The old time saying of supply and demand, the market forces that control costs in every sector of the American economy, are not present in an employer-based health care system. In sharp contrast

to Government-based insurance or mandatory employer-based insurance, where government bureaucrats or corporate officials are deciding what level of benefits Americans will receive, our bill will provide every American with the means to purchase health insurance within the framework of the free market and with consumer choice.

Under our bill, health insurance benefits will be made available to all Americans with the tax relief currently enjoyed by individuals with employer-provided insurance. However, this coverage will no longer be dependent upon employer status.

Furthermore, consumer choice would serve as a driving force in bringing down costs, the same way it does in the rest of our economy. This would be accomplished by transferring the multibillion-dollar Federal tax break for employers providing health benefits in the form of deductions and exclusions, and giving that money to American workers in the form of a Federal tax credit.

The Federal tax exclusion alone was worth \$66.6 billion in 1991 dollars for 1992. As members of this committee are aware, this legislation imposes a mandate on individuals to purchase, at a minimum, a health care package which must include catastrophic coverage to address the free rider problem. Every individual who fulfills this legal requirement will receive a Federal tax credit to offset the cost.

This new tax relief would also be extended to individuals and families for payment of out-of-pocket expenses. The tax credit would be provided directly through the tax withholding system, or through a voucher for the working poor. The size of the tax credit will vary according to a percentage of health care expenses in relation to an individual's adjusted gross income.

Mr. Chairman, by giving every individual the same tax advantages, irrespective of place of employment or income, and empowering them with tax credits to purchase insurance, a consumer choice system will enable Americans to seek the best value for their health care dollars when buying health insurance.

If private employers wish to continue providing health benefits to their employees, there is nothing, and I repeat, there is nothing in this legislation that would prevent them from doing so, and they can still continue to deduct the cost of providing that benefit. However, it should be noted that with equal tax treatment for all Americans who purchase health insurance, company plans will be competing with different types of health insurance packages, keeping prices down.

Mr. Chairman, at the risk of sounding redundant, I would like to emphasize to you that the core problem of our health care system is the Tax Code. And if we are to ever remedy the problem arising out of the current inequity, the Tax Code needs to be changed. By changing the Tax Code and empowering the individual directly, the health care market will be changed from an employer-based market to an individual-based market, as it should be.

By giving the American people what you and I have as Members of Congress enjoy, the power to choose our own health insurance plan and combining that power with widespread competition, our bill will offer constituents the best chance of controlling health care costs. And I would like to say also that our legislation has been



scored by Lewin-VHI, the same health firm that President Clinton used, that the administration used. It is budget neutral, deficit neutral, and does not raise taxes on Americans.

No price controls are employed, no global budgeting, no new bureaucracies are created, no monolithic alliances are set up under the purview of a national health care board. The major objection I have encountered to an individual mandate is that our citizens aren't capable of choosing their own health care plan. I couldn't disagree any stronger.

Even Enthoven, one of the architects of managed competition, a proposal that has been offered by our esteemed colleague from Tennessee, Mr. Cooper, has stated the following, and let me quote here. Quote, "Critics of the consumer choice position usually are not very explicit about whom they consider to be better qualified than the average American to choose his health plan for him."

I would like to point out that the Americans have made important decisions themselves before. They make decisions with respect to their mortgage policies, their car insurance policies, their life insurance policies, homeowners insurance policies, all without the creation of alliances, national health boards. Why? Because these matters are not employer-based.

When an individual loses his or her job, they do not lose their car insurance or go to a new mortgage company. There is no reason why a health insurance should be treated any differently.

While the changes to the Tax Code are the heart of this proposal, Senator Nickles and I have included several other key reforms which must be addressed in this debate. Antifraud measures are included to enhance Federal criminal penalties established against health care providers, and insurers who knowingly defraud persons in connection with a health care transaction.

Antitrust provisions have been included to create safe harbors from Federal antitrust laws for certain groups of providers, medical self-regulatory entities that do not operate for financial gain, certain joint ventures for high technology and costly equipment and services and hospital mergers. This is especially crucial for rural new hospitals forced to compete against each other for patients.

We also, Mr. Chairman, we have malpractice insurance reform. And, Mr. Chairman, this provision of malpractice that we have in our bill, is patterned after California medical malpractice law. So it has been in operation, I think, since 1976. There is administrative reforms, too. 1970, in there, yes.

Let me just conclude by mentioning three things about this bill. It would require health insurance policy to cover specific diseases, services or providers, limit the ability of managed-care plans to—let's see here. Let me start off again, Mr. Chairman.

Another important feature of this legislation is the explicit preemption of State laws which are deemed to be anti managed care laws. For example, the bill would preempt the State laws which require health insurance policies to cover specific diseases, services or providers, limit the ability of managed-care plans to selectively contract with health care providers, and third, limit the ability of managed-care plans to impose higher cost-sharing provisions on treatment obtained from providers outside of a plan's network.



Mr. WAXMAN. Mr. Stearns, I am going to commend you on this presentation, all of which is going to be in the record, and your hard work on this legislation. It is clear you have given it a great deal of thought. I think it is a constructive recommendation to the subcommittee.

You are a member of the full committee and Ranking Republican on the subcommittee that also has jurisdiction over this issue. I want to get a chance to review your legislation in detail and I am going to read over your comments and talk to you further about it. I think you have given us some good suggestions and I want to thank you for it.

[Testimony resumes on p. 198.]

[The opening statement of Mr. Stearns follows:]

**OPENING STATEMENT  
by the  
HONORABLE CLIFF STEARNS (R-FL)**

**Testimony before the House subcommittee on Health & Environment**

**February 2, 1994**

Thank you Mr. Chairman for allowing me this opportunity to testify before your subcommittee on H.R.3698 / S. 1743, the Consumer Choice Health Security Act of 1993, legislation I jointly introduced with Senator Don Nickles of Oklahoma. As the members of this committee are aware, the issue of health care reform has remained at the forefront of our citizens' concerns and rightfully so. In the President's State of the Union address we all heard him say that he would not sign into law a health care reform proposal that did not guarantee universal coverage. H.R. 3698 does that and more. As such, I believe that it merits full consideration by the Congress before a final bill is brought to the House floor for a vote.

I would like to quote the President from his State of the Union remarks.

*"The American people provide those of us in government service with terrific health care benefits at reasonable costs. We have health care that's always there. I think we need to give every hard working, taxpaying American the same health care security they have already given us."*

Mr. Chairman, members of this committee, over 40 of our colleagues here in the House and Senate agree with that statement. That is why we introduced the "Consumer Choice Health Security Act of 1993." As the title indicates, this legislation seeks to provide quality necessary medical care to all Americans through the oldest and proven mechanism -- the free market. Furthermore, this legislation is patterned after the Federal Employee Health Benefits Program (FEHBP) that has been in existence for over thirty years and held down costs while providing quality health plans.

As you know, all members of Congress, our staffs, the President, the Vice President, the cabinet, the Supreme Court Justices, and some ten million federal employees, retirees and dependents are enrolled in the FEHBP. The program is unique in that it is explicitly based on the free market principles of consumer choice and market competition.

Unlike our constituents, we have the luxury of being able to pick and choose from over thirty different health plans -- be it a traditional fee for service, HMO, PPO, or union sponsored plan like the postal workers etc. Unlike the rest of America, we get to make a personal choice and compare the prices, and level of benefits of each plan. We then make a decision based on our budget, our needs, and our bottom line, not some corporation's bottom line.

While the FEHBP model is not perfect, with the modifications that have been added in this bill, an FEHBP type system can be expanded to cover all Americans. Combined with an individual mandate that is explicitly written into this bill, the President's goal of universal coverage is met. The FEHBP is a sound program with good benefits. And while the level of benefits has increased over the years, costs for these plans have been effectively kept down. Not with price controls mind you. But with competition. On September 14, 1993, Jim King, the Director of Office of Personnel Management stated "Our enrollees continue to gain from the competition and managed care that form the backbone of the FEHBP program." This is evidenced by the fact that the price of premiums federal employees have to pay in 1994 are only 3% higher than the prices they paid in 1993.



In short, the market forces have worked for the FEHBP. There is no reason why these same principles cannot work for the American people. Most Americans are kept out of the picture when it comes to purchasing health insurance because it is usually purchased by their employer. Doctors and hospitals rarely discuss bills or fees prior to delivery of care and rely on third party reimbursement. Consumers are shielded from the true costs of health care and as such, there is no incentive for all parties involved to control costs. The time old saying of supply and demand -- the market forces that control costs in every other sector of the American economy are not present in an employer based health care system.

In sharp contrast to government based insurance or mandatory employer based insurance, where government bureaucrats or corporate officials are deciding what level of benefits Americans will receive, H.R. 3698 will provide every American with the means to purchase health insurance within the framework of the free market and consumer choice.

Under the Consumer Choice Health Security Act of 1993, health insurance benefits will be made available to all Americans along with

the tax relief currently enjoyed by individuals with employer provided insurance. However, this coverage will no longer be dependent on employment status. Furthermore, consumer choice would serve as a driving force in bringing down costs the same way it does in the rest of the economy. This would be accomplished by transferring the multi-billion dollar federal tax break for employers providing health benefits, in the form of deductions and exclusions - and giving that money to American workers in the form of a federal tax credit. The federal tax exclusion alone was worth \$66.6 billion in 1991 dollars for 1992.

As the members of this committee are aware, this legislation imposes a mandate on individuals to purchase at a minimum, a health care package which must include catastrophic coverage to address the free rider problem. Every individual who fulfills this legal requirement will receive a federal tax credit to offset the costs. This new tax relief would also be extended to individuals and families for payment of out-of-pocket medical expenses. The tax credit will be provided directly through the tax withholding system or through a voucher for the working poor. The size of the tax credit will vary according to a percentage of health care expenses in relation to an individual's

adjusted gross income.

By giving every individual the same tax advantages, irrespective of place of employment or income, and empowering them with tax credits to purchase insurance, a consumer choice system will enable Americans to seek the best value for their health care dollar when buying health insurance. If private employers wish to continue providing health benefits to their employees, there is nothing, I repeat, there is nothing, in this legislation that would prevent them from doing so and they can still continue to deduct the cost of providing that benefit. However, it should be noted that with equal tax treatment for all Americans who purchase health insurance, company plans will be competing with different types of health insurance packages and keep prices down.

At the risk of sounding redundant, I would like to emphasize that the core problem of our current health care system is the tax code, and if we are to ever remedy the problems arising out of the current inequity, the tax code needs to be changed. By changing the tax code and empowering the individual directly, the health care market will be changed from an employer based market to an individual based

market as it should be. By giving the American people what you and I as Members of Congress enjoy, the power to choose our own health insurance plan, and combining that power with widespread competition, H.R. 3698 will offer our constituents the best chance at controlling health care costs.

I would like to point out that this legislation has already been scored by Lewin-VHI, the same health econometrics firm used by the Clinton Administration. It is budget neutral, deficit neutral, and does not raise taxes on Americans. No price controls are employed, no global budgeting, no new bureaucracies are created, and no monopolistic alliances are set up under the purview of a National Health Board.

The major objection I have encountered to an individual mandate is that our citizens aren't capable of choosing their own health plan. I couldn't disagree any stronger. Even Alain Enthoven, one of the architects of "Managed Competition", a proposal that has been offered by our esteemed colleague from Tennessee, Mr. Cooper, has stated the following, and I quote:

*"Critics of the consumer choice position usually are not very explicit*



*about whom they consider to be better qualified than the average American to choose his health plan for him."*

- New England Journal of Medicine (1978)

I should point out that Americans make important decisions every day without delegating those responsibilities to government bureaucrats or politicians. They make decisions with respect to their mortgage policies, car insurance policies, life insurance policies, homeowner's insurance policies all without the creation of alliances, national health boards, or bureaucrats. Why? Because these matters are not employer based. When an individual loses his job, he does not lose his car insurance or go to a new mortgage company. There is no reason why health insurance should be treated any differently.

While the changes to the tax code are the heart of this proposal, Senator Nickles and I have included several other key reforms which must be addressed in this debate. Anti-fraud measures are included to enhance federal criminal penalties established against health care providers and insurers who knowingly defraud persons in connection with a health care transaction. Anti-trust provisions have been included to create "safe harbors" from federal anti-trust laws for certain groups of providers; medical self-regulatory entities that do

not operate for financial gain, certain joint ventures for high technology and costly equipment and services and hospital mergers. This is especially crucial for rural area hospitals forced to compete against each other for patients. In my district down in Florida, there have been instances in which a hospital will decide to purchase an MRI machine just so that it can advertise to the public that they have state of the art technology when just a few miles away, another hospital will have the same equipment already in place that could be used by the patients of that first hospital.

Long term care is addressed as well in this bill. H.R. 3698 also exempts from taxation certain exchanges of life insurance policies for long-term care policies, and amounts paid or advanced from a life insurance contract to a terminally or chronically ill individual who is confined to a hospice or nursing home.

Malpractice reforms are also included. The bill caps noneconomic damages at \$250,000, reduces the amount of damages paid in a medical malpractice case by the amount of other payments (such as private disability insurance or employer wage continuation program payments) made to the injured party for medical care, limits the

liability of manufacturers or sellers of health care products approved by the FDA, except in cases where the manufacturer withheld or misrepresented information to the FDA or bribed an official, and provides for a schedule of limits on attorney fees in medical malpractice actions:

1) 40% of the first \$50,000, 2) 33.3 % of the next \$50,000, 25% of the next \$500,000, and 15% of any additional award or settlement. Mr. Chairman, this provision may sound familiar because it is patterned after California medical malpractice law, also known as (MICRA). This law has been in effect since the mid 1970's and proven to bring down the number of frivolous claims while ensuring the residents of California who are harmed by a negligent doctor to be justly rewarded.

Administrative reforms are also included which are designed to reduce the amount of paperwork and double-billing the insurance industry and hospitals are famous for. Another important feature of this legislation is the explicit pre-emption of state laws which are deemed to be "anti-managed care" laws. For example, the bill would preempt state laws which:

1) require health insurance policies to cover specific diseases,

services, or providers;

2) limit the ability of managed care plans to selectively contract with health care providers;

3) limit the ability of managed care plans to impose higher cost sharing provisions on treatment obtained from providers outside a plan's network.

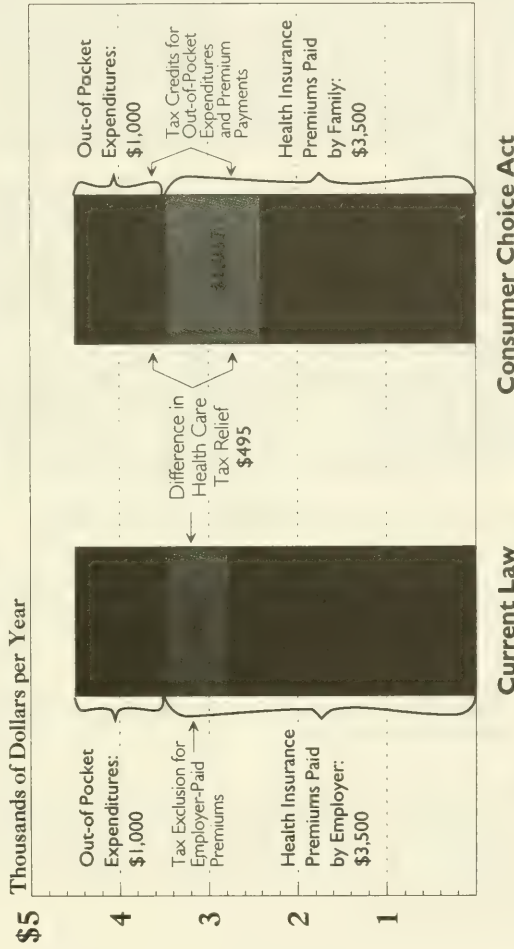
In conclusion, this legislation achieves universal coverage, provides portability, security, simplicity, and cost containment without raising taxes or the creation of powerful and potentially monopolistic alliances. Instead, it will allow all Americans a wide array of choices of benefits within many health plans, just like the system that is currently available to Administration officials and Members of Congress. The major cost constraint is a purely competitive health care market, something that has been sorely missing for the past five decades. Combined with personal responsibility and the security of knowing that they can purchase health insurance from plans they trust, such as their union, church, farm bureau, or employer, AND enjoying tax relief, this is an alternative that Americans will want to explore further.



As Members of Congress and members of the House Energy & Commerce Committee, we have been presented with an historic opportunity to rectify what is wrong with the health care system, and to maintain what is right. There is no need to subject one-seventh of the nation's economy to a new and untried scheme that has not been proven to hold down costs while continuing to provide quality medical care to our nation's citizens. We can resort to price controls, decisions coming down from bureaucrats in Washington, DC, and rationing. Or, we can open up the market and give every American the same benefits of choice and competition that Members of Congress enjoy.

Finally, if this Congress fails to give the American people the same benefits and advantages of a free market system of health care, then this Congress should be willing to deny themselves those same advantages and withdraw themselves from a market driven federal system - and enroll in whatever state run health program we force upon the rest of America. Thank you, Mr. Chairman.

## How the Nickles/Stearns Consumer Choice Health Reform Would Affect a Family of Four With an Income of \$35,000



Figures based on a hypothetical case study of the Smith family: husband, wife and two children. Family receives \$3,500 of health coverage through Mr. Smith's employer and incurs \$1,000 in out-of-pocket expenditures. Family is in 15% tax bracket and pays 7.65% FICA tax.

Mr. STEARNS. Well, I appreciate you allowing us to present it, put it in the record. You know, I would say that on our side of the aisle, Mr. Chairman, this is a plan that provides universal coverage. And I don't think many individuals are coming to you with a plan on our side with universal coverage to this, shall we say, as well thought out as this.

And I think in the long term, the idea of moving the employer-based mandate to an individual mandate, is something that you, I hope, will consider. And I know a little bit of how you feel on this debate, but I—if anything, I could leave you with, it is the thought that a mandate on employer is something that would not bring personal responsibility.

A requirement on individuals will give universal coverage and in that way will give personal responsibility. They will control the dollars that they can use in medical IRA's as well as buying their own health care. So let me just say in your heart of hearts, if you can look at this proposal and realize it is an alternative for universal coverage and almost every country, the further they go down with more government insurance, is some day going to have to return to the market and return to the idea of maybe a mandate on employees, on the individual, rather than the employer. I pose that as a closing argument.

Mr. WAXMAN. I appreciate that. I am certainly going to take that to heart.

Any questions by members of the committee?

Mr. Hall.

Mr. HALL. I think the chairman has stated very well. I like his ideas on consumer choice and using the free market. A lot of good stuff is in there that can probably merge into a final bill when we really write it, when we get one written.

Mr. WAXMAN. Thank you very much.

Mr. STEARNS. That would be terrific if the chairman would say he would merge part of this into the final bill, make that commitment.

Mr. WAXMAN. Well, I think we ought to continue to work together and to see if he can take the best of all of the items of legislation, and I want to work with you on that.

Mr. STEARNS. And I look forward to working with you. Thank you.

Mr. WAXMAN. Thank you.

Our final panel consists of four of our colleagues who are here to offer their perspectives on health care reform, the Honorable Ralph Regula of Ohio, the Honorable Ronald Coleman of Texas, the Honorable James Traficant of Ohio, the Honorable Rosa DeLauro of Connecticut.

I would like to ask each of you to come forward. We are pleased to have you all here and looking forward to your testimony. Your prepared statements are going to be in the record in full. There is not a sentence that is going to be left out. So if you don't get a chance to go over everything that is in it and want to just summarize, we wouldn't have any serious objections and you shouldn't feel as a consequence of that that we wouldn't have in the record your whole—all your thoughts on this.

We would like to ask you, if you would, to try to keep the oral presentation to around 5 minutes. This has been a very long day and we may even have some questions so we want a chance to ask those questions as well.

Mr. Regula, why don't we start with you. I am going to use the clock. It will tell you when the 5 minutes is up. And just so you have an idea of that time frame having passed, because I know sometimes it goes quicker than we might imagine.

Mr. HALL. You are not going to invoke the hook or anything?

**STATEMENT OF HON. RALPH REGULA, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO**

Mr. REGULA. Thank you, Mr. Chairman. I will be brief. I simply want to talk about the inclusion of preventive health care for senior citizens, because Medicare is a separate program in the proposal by the President. I think evidence is rather strong that preventive health care is a way of improving the quality of life while at the same time saving money.

For example, testing for hypertension and high blood cholesterol has proven very effective in reducing the death rate from heart disease and stroke by 10 to 25 percent. You, Mr. Chairman, and, of course, the chairman isn't here now, but he is among the 120 people who have cosponsored my bill, which would allow Medicare reimbursement for preventive health care benefits such as cervical, colon and breast cancer examinations.

Does it work? Legislation I sponsored as a demonstration project whereby flu shots were reimbursed under Medicare, was recently implemented by the Department of Health and Human Services, on a permanent basis because of the clear evidence that it saved thousands of lives, in addition to millions of dollars. The problems that come from respiratory diseases are especially severe in the case of seniors, and the flu shots, which are now Medicare reimbursed by law, have been very effective. And I think it illustrates the fact that if we can develop the other types of reimbursement under Medicare for preventive medicine tests, then we can save a lot of money in addition to improving the quality of life of our seniors.

So that is something I think ought to be included as part of any health care reform bill, to encourage the use of preventive medicine techniques. Not only for seniors, but for all people, because I believe the greatest gains we can make in reducing the cost of health care will be in pushing for preventive medicines. Thank you for your time.

[Testimony resumes on p. 232.]

[The prepared statement and attachments of Mr. Regula follow:]



FEBRUARY 2, 1994

STATEMENT OF THE HONORABLE RALPH REGULA, 16TH DISTRICT - OHIO  
BEFORE THE SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT,  
COMMITTEE ON ENERGY AND COMMERCE

Mr. Chairman:

Over a decade ago, the Surgeon General's report on Health Promotion & Disease Prevention stated, "Improvement in the health status of our citizens will not be made predominantly through the treatment of disease, but rather through its prevention."

I am here today for the sole purpose of reinforcing this idea, by recommending that coverage for preventive care must be part of any proposal for health care access to both the young and the old.

One of the best arguments for preventive care benefits can be determined by looking at the facts involved in one the major causes of death in the United States-- cardiovascular disease. In 1990, an estimated 392,000 coronary artery bypass procedures were performed on 262,000 patients at an estimated expenditure of over \$9 billion.

While we do not understand all the causes of heart disease, we can act on studies which show that increased blood cholesterol levels and hypertension are high risk factors of coronary heart disease.

In a recent national study, nearly 13,000 men and women were screened at 11

lipid research centers across the country. Roughly 25% had blood cholesterol levels throughout to place them at moderate risk of heart disease, defined as 200 milligrams per deciliter at age 20, 220 at age 30, and 240 at age 40 and above.

Scientists from the National Heart, Lung, and Blood Institute have reported that testing for hypertension can be effectively conducted in shopping centers, workplaces and schools. Moreover, the study found that nearly half of those people identified as "high risk" of heart disease will contact their physicians for follow-up care. Clearly, the successes of such tests have been repeatedly demonstrated. Since 1978, the death rate from heart disease and stroke has fallen 10% and 25% respectfully.

Common sense tells us that not only lives have been saved as a result of such preventive tests, but health care dollars have been saved as well.

Now I am fully aware that the majority of the main health care reform proposals (Clinton, Cooper/Grandy, etc.) include preventive health care. To that end, I praise those proposals.

Yet, in these same proposals, where Medicare is maintained as a separate program, preventive care is not consistently included as an expansion of Medicare benefits. Mr. Chairman, we must see to it that the elderly maintain the continuum we provide to the younger through health care reform.

In the past three Congresses, I have introduced legislation to require

Medicare to consider coverage of preventive health services to the elderly.

As a ranking Minority member on the Subcommittee of Health and Long Term Care on the former Select Committee on Aging, much of the work that was done supported the need for expanding Medicare to include an assortment of preventive health services. As you know, Medicare reimbursements are largely limited to the payment of pneumonia and hepatitis vaccinations, and more recently flu shots due to a demonstration project which I initiated.

In 1988, HCFA began implementing legislation which I had introduced requiring a nationwide demonstration project to test the effectiveness of flu shots. Last year over 20,000 lives were saved by the program with an estimated cost savings of \$63 million.

I am pleased to announce that last October, Secretary Shalala made the flu shot a permanent part of the program without further congressional consideration. The key to making flu shots effective is the point of delivery and targeting high-risk population subgroups. HCFA's accumulated data on this matter can provide a framework for determining the settings under which the benefit would be best reimbursed. An across-the-board reimbursement that does not establish such a framework will be a waste of precious tax-dollars.

Despite similar studies revealing how certain preventive health tests can significantly improve the quality and length of life in such diseases as colon, cervical, and breast cancer the government continues to refuse reimbursement for these treatments. My bill takes a common sense approach

to includes such tests, so that both lives and money will be saved.

I would like to raise two concerns with my legislation as it is currently drafted. I refer to the provisions regarding Medicare reimbursement for colorectal examinations and nutrition screening. These are both areas for which I have longstanding familiarity.

First, fecal blood stool tests should be reimbursed under Medicare.

Fecal stool blood tests are a recognized and reliable means for determining irregularities within both the upper and lower colon. However, because the test does not conclusively establish the presence of cancer, I would recommend to the Committee that consideration be given to making reimbursement for the flexible sigmoidoscopy conditional upon first a positive test result under the stool examination.

Second, I recommend that the Medicare reimburse for nutrition screening-- that is, a systematic method to identify those who are malnourished.

Older Americans are at a disproportionate risk of poor nutrition, whereby 25% of elderly patients and 50% percent of those hospitalized suffer from malnutrition. Elderly patients who are malnourished get more infections and diseases, their injuries take longer to heal, surgery on them is riskier, and their hospital stays are longer and more expensive.

The Nutrition Screening Initiative has developed and distributed materials to assist health care professionals and individuals themselves to identify



malnutrition. NSI estimates that for every \$1.00 spent on nutrition screening and services, we save at least \$3.25 in other health care costs.

Currently, reimbursement for nutrition screening and medical nutritional therapy, which can be used to treat malnutrition, has been limited because Medicare, using 1965 guidelines, covers medical nutrition therapy only when patients are hospitalized and the hospital chooses to provide the service. More recent clinical data demonstrates that medical nutritional therapy can help elderly patients avoid chronic and acute care and speed their recovery when they do get sick.

Mr. Chairman, I would like to comment on the fact that President's bill does include clinical visits and nutritional counseling. I stress that language should specifically reference nutrition screening and counseling.

We can do a great service by designing a preventive health care package for the young and the old. It makes no sense to spend money on care after the onset of an illness when prevention cuts costs and provides a better quality of life for all of us.

Medical science has brought to us the ability to preserve life far beyond that of our ancestors. But it is not enough to add years to life. Our objective must also be to add vibrancy to those years. Preventive health care can add that vibrancy not only through maintaining life, but maintaining it at a higher quality.

Thank you.

## NUTRITION SCREENING AND TREATMENT

## EXAMPLES OF COST SAVINGS

**Nutrition Services**

Nutrition services can save costs in a number of ways.

1. Elderly patients with chronic malnutrition often die of infections, most commonly pneumonia and urinary sepsis. Patients who have limited mental or physical ability quickly become dehydrated and dysfunctional. They require time for IV rehydration once hospitalized before their physical abilities can be evaluated. In a study of older patients admitted to a hospital, those who were malnourished had actual hospital charges double that of those who were not malnourished, and their average length of stay was 5.6 days longer than patients without malnutrition. Another study in a Pittsburgh hospital found that the presence of malnutrition resulted in increased variable costs to the hospital of \$9,715 per patient. A third study indicated that costs are four times higher for malnourished patients (\$3,000 compared to \$12,700).
  
2. On the other hand, adequately nourished patients have decreased morbidity/mortality and fewer secondary medical complications/diseases; wounds heal faster; fewer infections occur; and hospitalizations are shorter. These factors all reduce Medicare/Medicaid and other third-party payer costs. Optimum nutrition care is not only important in the prevention of complications. It is crucial in the progression of other therapies (physical, occupational, speech, etc.) and on the effect of medication on the patient's disease and recovery.
  
- Example 1: A 75 year old man with head and neck cancer worked with a Registered Dietitian during his two month radiation treatment program. Together they had a goal of maintaining his weight and preventing weight loss during the treatments. He actually gained weight during this time and his nutritional status remained stable. He was able to eat a modified diet and utilized nutrition supplements as needed. He was able to have almost continuous treatments since his nutrition status was so good. The typical scenario for most patients undergoing radiation treatments is to lose weight and end up on enteral tube feedings. The initial placement of a feeding tube requires hospitalization none of which was needed in this case.
  
3. Patients in nursing homes are often malnourished on admission and are frequently on tube feedings that require the nutritional expertise of a Registered Dietitian to determine the balance of nutrients and fluid. In addition, many older Americans are referred for home health care for a lifetime of tube feeding due to dysphagia, confusion, coma, etc. Often, the initial order needs to be adjusted to meet the patient's actual nutrient needs that are coordinated with other aspects of their medical treatment and care.

Example: In 1988 a 61 year old Maryland woman lost 54 pounds in one month. She was referred to several physicians and psychiatrists and even spent one week in a psychiatric unit and yet no one could determine the cause of her problem. Finally a physician diagnosed her as having "pseudo obstruction", a disease that mimics intestinal blockage but is seldom found through routine diagnostic procedures. He started her on an intravenous (parenteral) feeding system that bypassed the digestive tract and her weight and health returned. A Registered Dietitian was called in to do an assessment and found that the patient was able to tolerate a less invasive feeding through a tube inserted into the small intestine. This type of feeding (enteral feeding) is associated with fewer complications and costs \$200-300 per month compared to the parenteral nutrition which costs \$4,000-5,000 per month. This woman will need nutritional assistance for the rest of her life and the change to an enteral feeding will result in a considerable amount of savings.

4. The average cost of treating a pressure sore (decubiti ulcer) is \$15,000. Home health care data show an increase in the number of patients at home with pressure ulcers. Long term care facilities and hospitals also see problems with pressure ulcers when residents are malnourished, especially on admission. Patients with malnutrition on admission to hospitals had more pressure ulcers than those who were not malnourished. Furthermore, those who received nutritional supplementation healed faster than those who did not. The development of pressure ulcers correlates directly with incidence of protein-calorie malnutrition and is one of the practice guidelines being developed by the Agency for Health Care Policy Research.

A recent study found that 70% of all pressure sore patients on oral intake needed additional commercial meal replacements to meet the nutritional requirements for ulcer treatment. Thirty-four percent of all pressure sore patients required enteral or parenteral nutritional support. Ideally, the prevention and treatment of pressure sores should be the joint responsibility of the entire health care team - nursing staff, Registered Dietitian, and physician.

Example: While attending pressure sore rounds in a Philadelphia nursing home, a Registered Dietitian recommended a high protein feeding for a resident with severe (Stage III) ulcers. The wounds healed without further surgical intervention which could have cost up to \$10,000.

5. Older persons with diabetes who receive nutrition services control their diabetes and blood sugars better and have fewer hospital admissions. Nutrition affects the outcome of diabetes mellitus directly through control of body weight, blood glucose, and blood lipid levels (cholesterol and triglyceride) and indirectly by decreasing blood pressure.

Example: A woman in Atlanta with Type II diabetes and elevated cholesterol and triglycerides was treated with oral hypoglycemic agents

and lipid lowering drugs, but still had elevated blood glucose. Following four sessions with a Registered Dietitian for nutrition management, the patient lost 25 pounds, her blood glucose and lipid levels were acceptable, and no medication was needed. The nutrition management consisted of a low fat, low cholesterol diabetic diet with emphasis on changing eating habits. The net savings for just one year were \$1,050 (Cost of medications for one year was \$1,200 minus the cost of four Registered Dietitian visits at \$150).

6. Nutrition services are an integral part of medical treatment for renal patients. The provision of nutrition services help delay the progression of the disease and help the patient maintain or improve his/her nutritional status while on dialysis.

Example: A 65 year old male with uncontrolled hypertension and Type II diabetes was referred to a licensed, Registered Dietitian in Atlanta. The nutritional therapy consisted of a diabetic diet with protein, sodium, and potassium restrictions. The nutritional intervention was an attempt to "buy time" before placing the patient on hemodialysis. Following two sessions with the Registered Dietitian, the patient was able to delay dialysis treatments for four months. The cost of the nutrition therapy was \$90 and the cost of the 64 hemodialysis treatments that were avoided cost \$345 per treatment x 14 times a month x 4 months for a total of \$19,320. Nutrition therapy netted a cost savings of \$19,230.



**TO:** Nutrition Screening Initiative

**FROM:** Peter D. Hart Research Associates, Inc.

**DATE:** April 15, 1993

**SUBJECT:** National Survey on Nutrition Screening and Treatment for the Elderly

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*Between April 1 and 8, 1993, Peter D. Hart Research Associates conducted a national telephone survey among 757 health care providers and administrators who care for America's elderly population. The survey includes five types of health care professionals who fall into two broad categories and were selected for their familiarity with the health care needs of the elderly: health care providers, including gerontological doctors (132 interviews) and nurses (101), and health care administrators for hospitals (202), nursing homes (217), and home care agencies (105). The Methodological Appendix enumerates the five samples used in this project.*

The results from this survey can be summarized in the five following main points:

- ☛ **Malnourishment is a serious problem that affects a substantial proportion of elderly people in the United States. Taken together, gerontological doctors and nurses estimate that one in four of their own patients suffer from malnutrition and that fully one-half of the elderly patients in hospitals are malnourished.**
- ☛ **Doctors and nurses who specialize in geriatrics and the administrators who run America's hospitals, nursing homes, and home care agencies agree that nutrition plays a major role in the prevention, treatment, and recovery from illness and disease.**
- ☛ **Gerontological doctors and nurses and health care administrators widely agree on the cost-effectiveness of routine nutrition screening and treatment for the elderly population.**
- ☛ **One of the biggest obstacles to routine nutrition screening and early nutrition intervention is the lack of reimbursement to health care providers.**
- ☛ **There is broad consensus among those who care for America's elderly population that nutrition screening and treatment should be part of a basic benefits package and should be reimbursed by the government and other third-party payers.**

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**Memo on Survey Results--Nutrition Screening Initiative**  
**Page 2**

The consistency of results across all five types of health care professionals provides crucial support for the reliability of these conclusions. Indeed, the similarities in attitudes and perceptions among these groups invariably outweigh the differences in the exact proportions who emphasize the role of nutrition, the extent of malnutrition, and the cost-effectiveness of a program of nutrition screening and treatment.

**1. Malnourishment is a serious problem among America's elderly population.** We turned to doctors, nurses, and administrators who specialize in the care of the elderly to be our "eyes and ears" when it comes to the incidence of malnutrition among the population age 65 and over. After defining "malnourishment" as "a state in which, because of deficiencies, excesses, or imbalances in food or diet, someone is not getting proper nutrients, which weakens his or her body and is harmful to his or her health," gerontological doctors and nurses and health care administrators were asked their perception of the proportion of hospital patients, nursing home residents, home care recipients, and their own patients who are malnourished.

As the following table demonstrates, these gerontological doctors and nurses and health care administrators provide disturbing estimates of the number of elderly Americans suffering from malnourishment. Doctors and nurses who specialize in caring for the elderly estimate that approximately one-half of all elderly

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hospital patients are malnourished, as are more than two in five nursing home residents.

**Table 1: Estimate of the Extent of Malnutrition  
among Selected Elderly Populations**

	<b>Median %</b>
<b>Elderly hospital patients</b>	
Nurses	57
Doctors	43
Hospital administrators	34
<b>Nursing home residents</b>	
Doctors	50
Nurses	38
Nursing home administrators	25
<b>Home care recipients</b>	
Home care administrators	44
<b>Their own patients</b>	
Nurses	28
Doctors	26

Even hospital administrators estimate the proportion of elderly patients in hospitals who are malnourished at one in three; nursing home administrators judge the proportion of malnourished nursing home residents to be one in four; and home care administrators think that more than two in five of the elderly people receiving home care assistance are malnourished.

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Most striking is the estimate by gerontological nurses and doctors that more than one in four of *their own patients* are not receiving proper nutrients to such an extent that it is weakening their bodies and harmful to their health.

**2. Doctors, nurses, and health care administrators who care for America's elderly population widely agree that nutrition plays a major role in the prevention, treatment, and recovery from illness and disease.** As the following table illustrates, few of the providers and administrators assign nutrition the most important role in prevention, treatment, and recovery, but these health care professionals do express an extraordinary degree of consensus that nutrition plays a major rather than a minor role in the prevention, treatment, and recovery from illness and disease among the elderly.

**Table 2: The Role of Nutrition in Health Care**

	<b>Doctors/ Nurses %</b>	<b>Admin- istrators %</b>
<b>Prevention</b>		
The most important role	15	19
A major role	80	77
A minor role/not much of a role	5	4
<b>Treatment</b>		
The most important role	6	8
A major role	84	80
A minor role/not much of a role	10	11
<b>Promoting recovery</b>		
The most important role	18	12
A major role	80	83
A minor role/not much of a role	2	4

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Nutrition's vital role is also illustrated by the importance that health care administrators and providers attach to nutrition screening. Indeed, a majority of hospital and home care administrators, two-thirds of gerontological doctors, and three-fourths of gerontological nurses and nursing home administrators think it is important to ask about diet, eating habits, and weight loss, as well as conducting more intrusive assessments, such as blood tests, blood cholesterol tests, and measurements of body fat, when elderly people are admitted to hospitals, nursing homes, and home care agencies.

Indeed, a majority of gerontological nurses, nursing home administrators, and home care administrators, and a plurality of doctors and hospital administrators believe that more than 90% of elderly hospital patients, nursing home residents, and home care recipients would benefit from routine nutrition screening upon admission. Moreover, similar proportions of gerontological doctors and nurses and health care professionals in this survey believe that four in five of all elderly people in the United States who are living on their own would benefit from periodic nutrition screening and appropriate treatment.

**3. Health care professionals who specialize in geriatrics and the people who run America's hospitals, nursing homes, and home care agencies agree on the cost-effectiveness of routine nutrition screening and treatment, both for their own patients and as part of the health care system for the elderly**

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**population in general.** "Cost-effectiveness" was defined in this survey as "the extent to which the savings from fewer illnesses and more complete and rapid recoveries would offset the cost of a nutrition screening and treatment program." As the following table demonstrates, virtually four in five administrators and gerontological doctors and nurses think it would be cost-effective to provide routine nutrition screening and treatment for their patients, and similar proportions believe it would be cost-effective for the health care system in general to provide nutrition screening and treatment for all elderly people in this country. Fewer than one in five believe it would *not* be cost-effective to have a comprehensive program of nutrition screening and treatment for the elderly.

**Table 3: The Cost-effectiveness of Nutrition Screening and Treatment**

	<u>Admin- istrators</u> %	<u>Doctors/ Nurses</u> %
<b>Routine screening and treatment for their own patients</b>		
Definitely cost-effective	40	49
Probably cost-effective	38	35
Probably not cost-effective	14	9
Definitely not cost-effective	5	2
<b>Routine screening and treatment for all elderly people</b>		
Definitely cost-effective	35	43
Probably cost-effective	45	39
Probably not cost-effective	13	13
Definitely not cost-effective	4	2

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The health care professionals in this study were also asked to evaluate the importance of several arguments in favor of conducting nutrition screenings and implementing appropriate and early nutrition intervention for elderly patients under their care. The following table shows that a majority of gerontological doctors and nurses believe that reducing the number and duration of pressure ulcers, reducing complications, and promoting faster wound healing are all *extremely* important reasons for conducting nutrition screening and treatment. A majority of the health care administrators agree with providers when it comes to the beneficial effects of nutrition on pressure ulcers and faster healing, but they also regard the argument that prevention is less costly than treatment as an *extremely* important argument in favor of nutrition screening and early intervention.

**Table 4: Assessments of the Importance of Selected Reasons for Conducting Nutrition Screenings and Implementing Nutrition Intervention for Elderly Patients**

	<i>Extremely Important Reason</i>	
	<u>Admin-istrators</u> %	<u>Doctors/Nurses</u> %
Adequately nourished patients tend to have fewer pressure ulcers and to recover from them faster than do malnourished patients	58	68
Adequately nourished patients experience faster wound healing after surgery	53	62
It is significantly less costly to prevent malnutrition than to treat it	53	56
Malnourished patients have three times as many major complications as do adequately nourished patients	49	59
Health care facilities can save thousands of dollars caring for an adequately nourished patient rather than a malnourished patient who recovers more slowly and can develop complications	46	57
Malnourished patients stay in health care facilities two-thirds longer than do adequately nourished patients	44	55

**4. One of the biggest obstacles to routine nutrition screening and early intervention is the lack of reimbursement to health care providers.** The health care administrators and doctors and nurses in this study were asked to rate how much of a factor six reasons are for why nutrition screenings and early nutrition interventions are not routinely performed. As the following table shows, health care administrators place the most emphasis on the cost and lack of direct

## Memo on Survey Results--Nutrition Screening Initiative

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reimbursement for nutrition screenings and early intervention, especially those administrators in charge of home care agencies.

**Table 5: Reasons Why Nutrition Screenings and Early Intervention Are Not Routinely Performed**

	Single Biggest or Major Factor	
	<u>Admin-istrators</u> %	<u>Doctors/Nurses</u> %
The cost of the procedure and lack of direct reimbursement	62	46
Doctors do not request or emphasize nutrition screenings and treatments	51	55
Most institutions are not informed well enough to follow up properly on the results of nutrition screenings	34	34
A shortage of staff and qualified personnel	31	32
A shortage of registered or licensed dietitians	29	20
There is no proven need for nutrition screenings or scientific evidence of their benefit	17	19

The gerontological doctors and nurses place this reason--the cost of the procedure--second on their list of factors; both the nurses and the doctors themselves assign greater importance to doctors' failure to emphasize nutrition screenings and treatments. Overall, a clear majority of the doctors and nurses and three-fourths or more of the administrators believe that nutrition screening and appropriate treatments for malnourished patients would be routinely performed if the costs were reimbursed.

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5. A broad consensus exists among those who care for America's elderly population that nutrition screening and treatment should be part of the basic benefits package included in comprehensive health care reform and should be reimbursed by the government and other third-party payers. As the following table shows, health care professionals in this study overwhelmingly believe that routine nutrition screening and treatment should be reimbursed and that these measures should be part of the emerging package of comprehensive health care reforms.

Table 6: Coverage of Routine Nutrition Screening and Treatment

	Doctors %	Nurses %	Hospital Admin- istrators %	Nursing Home Admin- istrators %	Home Care Admin- istrators %
Should be part of the basic benefits package being developed as part of comprehensive health care reform	74	90	82	86	88
Should be reimbursed by the government or other third-party payers	83	89	88	86	87

This high degree of consensus on the appropriateness of reimbursing nutrition screening and treatment costs, and including these measures in a basic benefits package is entirely consistent with all the other data in this study, which shows the extent to which these health care professionals believe that malnutrition exists among the elderly, understand the importance of nutrition in the prevention, treatment, and recovery from illness and disease, and recognize the cost-effectiveness of nutrition screening and early intervention to treat malnutrition.

## Methodological Appendix

*This survey consists of the five samples listed in the following table.*

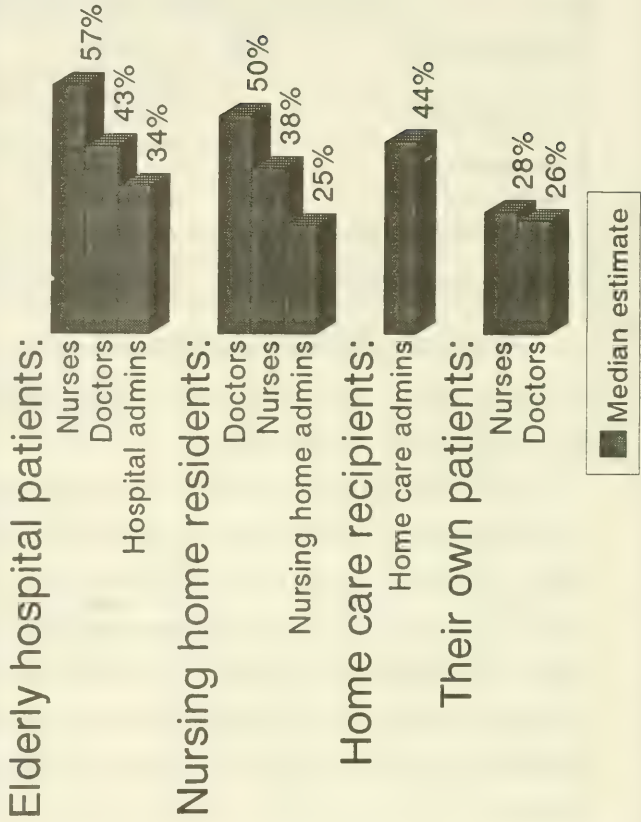
Samples Used in the Survey of Health Care Professionals Providing Care for the Elderly Population of the United States		
<u>Type of Respondent</u>	<u>Sample Size</u>	<u>Source of List</u>
Gerontological Doctors	132	Members of the American Geriatric Society engaged in family practice or internal medicine
Gerontological Nurses	101	Members of the National Gerontological Nurses Association
Hospital Administrators	202	SMG Hospital Market Database
Nursing Home Administrators	217	SMG Nursing Home Market Database
Home Care Agency Administrators	105	Home care agency members of the National Association of Home Care

*More than 90% of the health care administrators in this survey hold one of the top three positions in the "chain of command" in their institution; more than 80% are among the top two administrators.*

*The administrators and health care providers do, in fact, run institutions that care for the elderly. Seventy percent of hospital administrators say that 50% or more of their patients are age 65 and over; 83% of the home care administrators report that 70% or more of the people they serve are age 65 or over; 89% of the nursing home administrators say that 90% or more of their residents are at least 65 years old. In addition, 70% of doctors report that at least 80% of their patients are age 65 and over; the same is true of two-thirds of the nurses interviewed in this survey.*

*The three samples of administrators were weighted according to the number of hospitals, nursing homes, and home care agencies in the United States in order to form a representative sample of health care administrators dealing with the nation's elderly population. The samples of nurses and doctors were weighted according to the ratio of registered nurses to licensed physicians.*

## Estimated Proportion Of Malnourished People Among America's Elderly Population



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# The Role Of Nutrition In Health Care

## Prevention:



## Treatment:



## Recovery:



☒ Most important role
 ☐ Major role
 ☐ Minor role/no role

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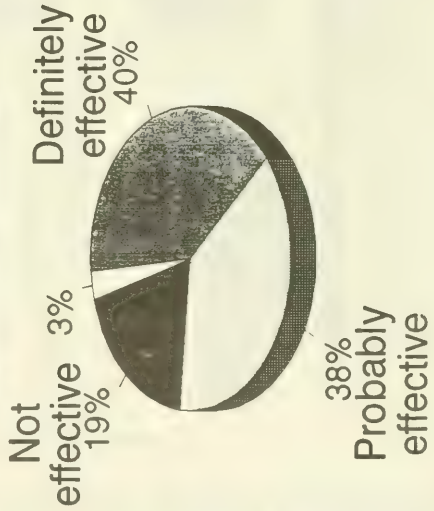


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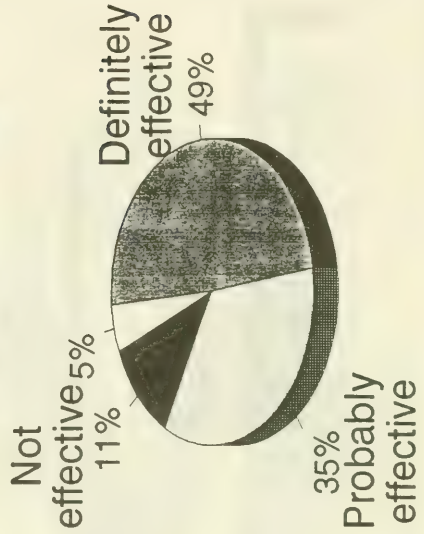


# Perceived Cost-effectiveness Of Nutrition Screening And Treatment For Their Own Patients

Administrators



Doctors/Nurses

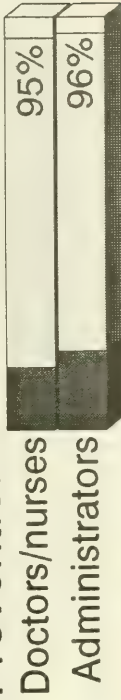


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# The Role Of Nutrition In Health Care

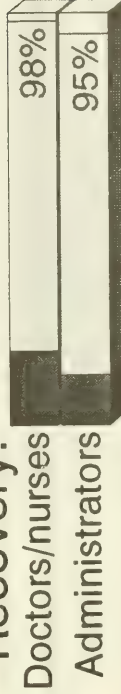
## Prevention:



## Treatment:



## Recovery:



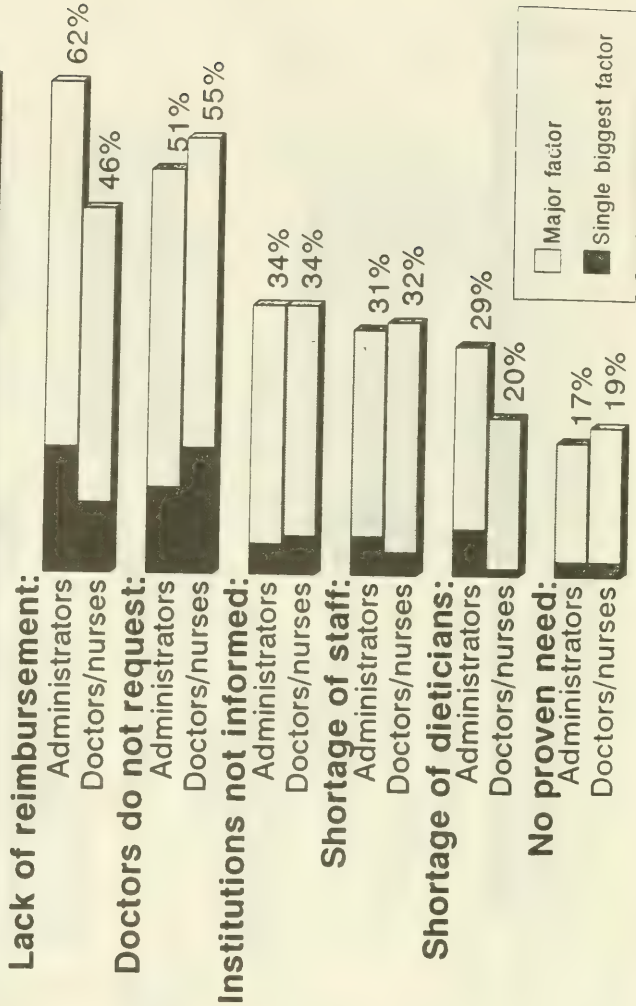
☒ Most important role
 ☐ Major role
 ☐ Minor role/no role

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## Reasons Nutrition Screening And Intervention Are Not Routine

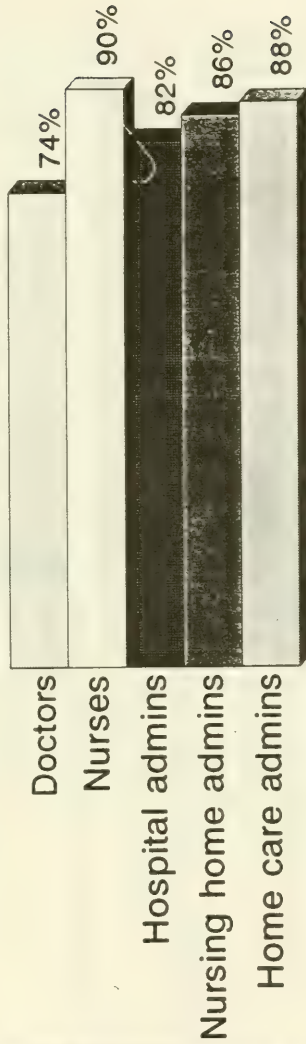


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## Nutrition Screening & Treatment Should Be Part Of Basic Benefits Package



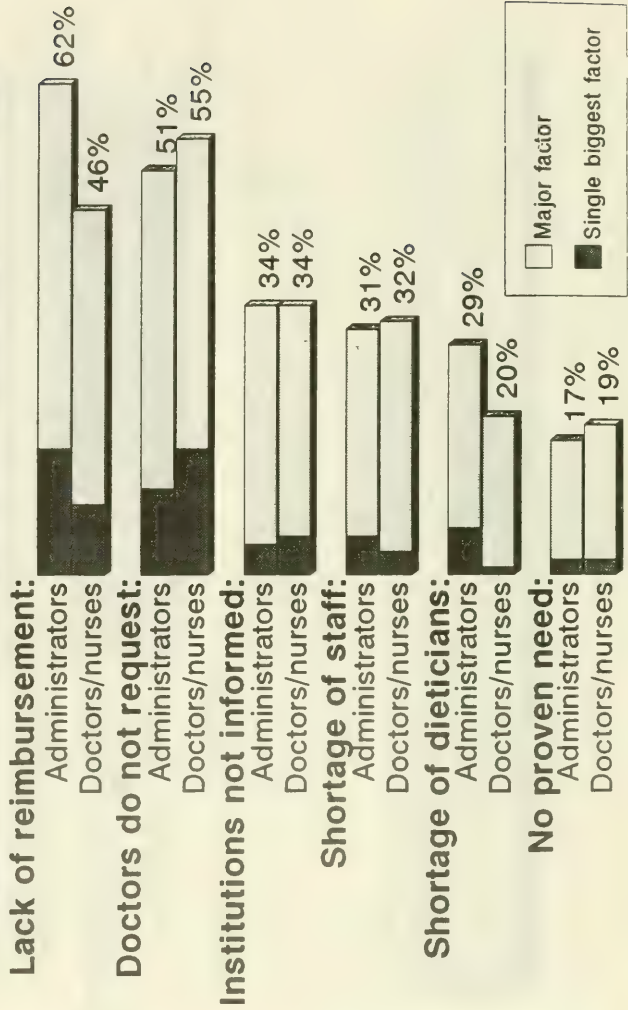
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## Reasons Nutrition Screening And Intervention Are Not Routine

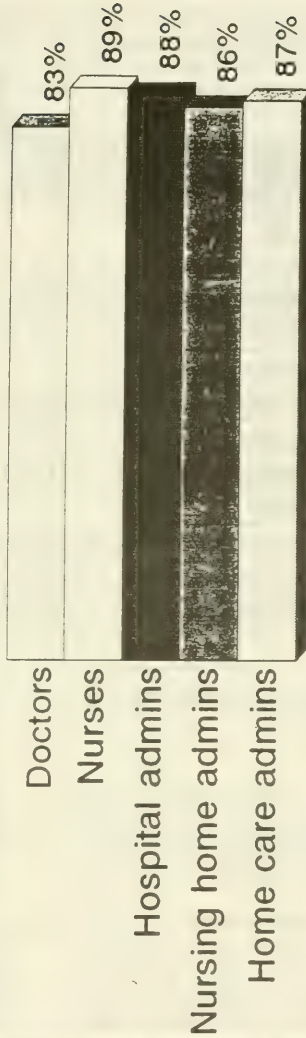


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## Nutrition Screening & Treatment Should Be Reimbursed



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*The Warning Signs of poor nutritional health are often overlooked. Use this checklist to find out if you or someone you know is at nutritional risk.*

Read the statements below. Circle the number in the yes column for those that apply to you or someone you know. For each yes answer, score the number in the box. Total your nutritional score.

## DETERMINE YOUR NUTRITIONAL HEALTH

	YES
I have an illness or condition that made me change the kind and/or amount of food I eat.	2
I eat fewer than 2 meals per day.	3
I eat few fruits or vegetables, or milk products.	2
I have 3 or more drinks of beer, liquor or wine almost every day.	2
I have tooth or mouth problems that make it hard for me to eat.	2
I don't always have enough money to buy the food I need.	4
I eat alone most of the time.	1
I take 3 or more different prescribed or over-the-counter drugs a day.	1
Without wanting to, I have lost or gained 10 pounds in the last 6 months.	2
I am not always physically able to shop, cook and/or feed myself.	2
<b>TOTAL</b>	

### Total Your Nutritional Score. If it's —

**0-2** **Good!** Recheck your nutritional score in 6 months.

**3-5** **You are at moderate nutritional risk.** See what can be done to improve your eating habits and lifestyle. Your office on aging, senior nutrition program, senior citizens center or health department can help. Recheck your nutritional score in 3 months.

**6 or more** **You are at high nutritional risk.** Bring this checklist the next time you see your doctor, dietitian or other qualified health or social service professional. Talk with them about any problems you may have. Ask for help to improve your nutritional health.

*These materials developed and distributed by the Nutrition Screening Initiative, a project of:*



AMERICAN ACADEMY  
OF FAMILY PHYSICIANS



THE AMERICAN  
DIETETIC ASSOCIATION



NATIONAL COUNCIL  
ON THE AGING, INC.

**Remember that warning signs suggest risk, but do not represent diagnosis of any condition. Turn the page to learn more about the Warning Signs of poor nutritional health.**

**The Nutrition Checklist is based on the Warning Signs described below. Use the word DETERMINE to remind you of the Warning Signs.**

## **D**ISEASE

Any disease, illness or chronic condition which causes you to change the way you eat, or makes it hard for you to eat, puts your nutritional health at risk. Four out of five adults have chronic diseases that are affected by diet. Confusion or memory loss that keeps getting worse is estimated to affect one out of five or more of older adults. This can make it hard to remember what, when or if you've eaten. Feeling sad or depressed, which happens to about one in eight older adults, can cause big changes in appetite, digestion, energy level, weight and well-being.

## **E**EATING POORLY

Eating too little and eating too much both lead to poor health. Eating the same foods day after day or not eating fruit, vegetables, and milk products daily will also cause poor nutritional health. One in five adults skip meals daily. Only 13% of adults eat the minimum amount of fruit and vegetables needed. One in four older adults drink too much alcohol. Many health problems become worse if you drink more than one or two alcoholic beverages per day.

## **T**TOOTH LOSS/ MOUTH PAIN

A healthy mouth, teeth and gums are needed to eat. Missing, loose or rotten teeth or dentures which don't fit well or cause mouth sores make it hard to eat.

## **E**CONOMIC HARDSHIP

As many as 40% of older Americans have incomes of less than \$6,000 per year. Having less--or choosing to spend less--than \$25-30 per week for food makes it very hard to get the foods you need to stay healthy.

## **R**EDUCED SOCIAL CONTACT

One-third of all older people live alone. Being with people daily has a positive effect on morale, well-being and eating.

## **M**ULTIPLE MEDICINES

Many older Americans must take medicines for health problems. Almost half of older Americans take multiple medicines daily. Growing old may change the way we respond to drugs. The more medicines you take, the greater the chance for side effects such as increased or decreased appetite, change in taste, constipation, weakness, drowsiness, diarrhea, nausea, and others. Vitamins or minerals when taken in large doses act like drugs and can cause harm. Alert your doctor to everything you take.

## **I**NVOLUNTARY WEIGHT LOSS/GAIN

Losing or gaining a lot of weight when you are not trying to do so is an important warning sign that must not be ignored. Being overweight or underweight also increases your chance of poor health.

## **N**EEDS ASSISTANCE IN SELF CARE

Although most older people are able to eat, one of every five have trouble walking, shopping, buying and cooking food, especially as they get older.

## **E**LDER YEARS ABOVE AGE 80

Most older people lead full and productive lives. But as age increases, risk of frailty and health problems increase. Checking your nutritional health regularly makes good sense.



The Nutrition Screening Initiative, 2626 Pennsylvania Avenue, NW, Suite 301, Washington, DC 20037

The Nutrition Screening Initiative is funded in part by a grant from Ross Laboratories, a division of Abbott Laboratories.



## Level 1 Screen

### Body Weight

Measure height to the nearest inch and weight to the nearest pound. Record the values below and mark them on the Body Mass Index (BMI) scale to the right. Then use a straight edge (ruler) to connect the two points and circle the spot where this straight line crosses the center line (body mass index). Record the number below.

Healthy older adults should have a BMI between 24 and 27.

Height (in): \_\_\_\_\_

Weight (lbs): \_\_\_\_\_

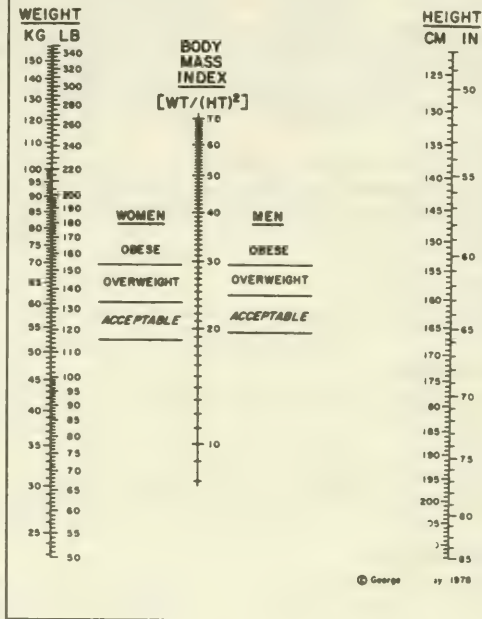
Body Mass Index: \_\_\_\_\_  
(number from center column)

Check any boxes that are true for the individual:

- ☐ Has lost or gained 10 pounds (or more) in the past 6 months.
- ☐ Body mass index <24
- ☐ Body mass index >27

For the remaining sections, please ask the individual which of the statements (if any) is true for him or her and place a check by each that applies.

NOMOGRAM FOR BODY MASS INDEX



LEVEL 1 SCREEN

Name: \_\_\_\_\_

Date: \_\_\_\_\_

### Eating Habits

- ☐ Does not have enough food to eat each day
- ☐ Usually eats alone
- ☐ Does not eat anything on one or more days each month
- ☐ Has poor appetite
- ☐ Is on a special diet
- ☐ Eats vegetables two or fewer times daily
- ☐ Eats milk or milk products once or not at all daily
- ☐ Eats fruit or drinks fruit juice once or not at all daily
- ☐ Eats breads, cereals, pasta, rice, or other grains five or fewer times daily
- ☐ Has difficulty chewing or swallowing
- ☐ Has more than one alcoholic drink per day (if woman); more than two drinks per day (if man)
- ☐ Has pain in mouth, teeth, or gums

***A physician should be contacted if the individual has gained or lost 10 pounds unexpectedly or without intending to during the past 6 months. A physician should also be notified if the individual's body mass index is above 27 or below 24.***

#### Living Environment

- ☐ Lives on an income of less than \$6000 per year (per individual in the household)
- ☐ Lives alone
- ☐ Is housebound
- ☐ Is concerned about home security
- ☐ Lives in a home with inadequate heating or cooling
- ☐ Does not have a stove and/or refrigerator
- ☐ Is unable or prefers not to spend money on food (<\$25-30 per person spent on food each week)

#### Functional Status

Usually or always needs assistance with (check each that apply):

- ☐ Bathing
- ☐ Dressing
- ☐ Grooming
- ☐ Toileting
- ☐ Eating
- ☐ Walking or moving about
- ☐ Traveling (outside the home)
- ☐ Preparing food
- ☐ Shopping for food or other necessities

If you have checked one or more statements on this screen, the individual you have interviewed may be at risk for poor nutritional status. Please refer this individual to the appropriate health care or social service professional in your area. For example, a dietitian should be contacted for problems with selecting, preparing, or eating a healthy diet, or a dentist if the individual experiences pain or difficulty when chewing or swallowing. Those individuals whose income, lifestyle, or functional status may endanger their nutritional and overall health should be referred to available community services: home-delivered meals, congregate meal programs, transportation services, counseling services (alcohol abuse, depression, bereavement, etc.), home health care agencies, day care programs, etc.

Please repeat this screen at least once each year—sooner if the individual has a major change in his or her health, income, immediate family (e.g., spouse dies), or functional status.

These materials developed by the Nutrition Screening Initiative.

## Level II Screen

Complete the following screen by interviewing the patient directly and/or by referring to the patient chart. If you do not routinely perform all of the described tests or ask all of the listed questions, please consider including them but do not be concerned if the entire screen is not completed. Please try to conduct a minimal screen on as many older patients as possible, and please try to collect serial measurements, which are extremely valuable in monitoring nutritional status. Please refer to the manual for additional information.

### Anthropometrics

Measure height to the nearest inch and weight to the nearest pound. Record the values below and mark them on the Body Mass Index (BMI) scale to the right. Then use a straight edge (paper, ruler) to connect the two points and circle the spot where this straight line crosses the center line (body mass index). Record the number below; healthy older adults should have a BMI between 24 and 27; check the appropriate box to flag an abnormally high or low value.

Height (in): \_\_\_\_\_

Weight (lbs): \_\_\_\_\_

Body Mass Index  
(weight/height<sup>2</sup>): \_\_\_\_\_

Please place a check by any statement regarding BMI and recent weight loss that is true for the patient.

- ☐ Body mass index <24
- ☐ Body mass index >27
- ☐ Has lost or gained 10 pounds (or more) of body weight in the past 6 months

Record the measurement of mid-arm circumference to the nearest 0.1 centimeter and of triceps skinfold to the nearest 2 millimeters.

Mid-Arm Circumference (cm): \_\_\_\_\_

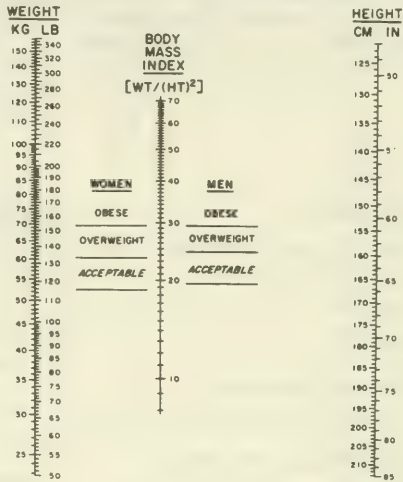
Triceps Skinfold (mm): \_\_\_\_\_

Mid-Arm Muscle Circumference (cm): \_\_\_\_\_

Refer to the table and check any abnormal values:

- ☐ Mid-arm muscle circumference <10th percentile

NOMOGRAM FOR BODY MASS INDEX



© George A. Bray 1978

- ☐ Triceps skinfold <10th percentile

- ☐ Triceps skinfold >95th percentile

Note: mid-arm circumference (cm) - (0.314 x triceps skinfold (mm)) = mid-arm muscle circumference (cm)

For the remaining sections, please place a check by any statements that are true for the patient.

### Laboratory Data

- ☐ Serum albumin below 3.5 g/dl
- ☐ Serum cholesterol below 160 mg/dl
- ☐ Serum cholesterol above 240 mg/dl

### Drug Use

- ☐ Three or more prescription drugs, OTC medications, and/or vitamin/mineral supplements daily

LEVEL II SCREEN

Name: \_\_\_\_\_

Date: \_\_\_\_\_

**Clinical Features**

Presence of (check each that apply):

- ☐ Problems with mouth, teeth, or gums
- ☐ Difficulty chewing
- ☐ Difficulty swallowing
- ☐ Angular stomatitis
- ☐ Glossitis
- ☐ History of bone pain
- ☐ History of bone fractures
- ☐ Skin changes (dry, loose, nonspecific lesions, edema)

Percentile	Men		Women	
	55-65 y	65-75 y	55-65 y	65-75 y
<b>Arm circumference (cm)</b>				
10th	27.3	26.3	25.7	25.2
50th	31.7	30.7	30.3	29.9
95th	36.9	35.5	38.5	37.3
<b>Arm muscle circumference (cm)</b>				
10th	24.5	23.5	19.6	19.5
50th	27.8	26.8	22.5	22.5
95th	32.0	30.6	28.0	27.9
<b>Triceps skinfold (mm)</b>				
10th	6	6	16	14
50th	11	11	25	24
95th	22	22	38	36

From: Friesen AR. New norms of upper limb fat and muscle areas for assessment of nutritional status. *Am J Clin Nutr* 1981; 34:2540-2545. © 1981 American Society for Clinical Nutrition.

**Eating Habits**

- ☐ Does not have enough food to eat each day
- ☐ Usually eats alone
- ☐ Does not eat anything on one or more days each month
- ☐ Has poor appetite
- ☐ Is on a special diet
- ☐ Eats vegetables two or fewer times daily
- ☐ Eats milk or milk products once or not at all daily
- ☐ Eats fruit or drinks fruit juice once or not at all daily
- ☐ Eats breads, cereals, pasta, rice, or other grains five or fewer times daily
- ☐ Has more than one alcoholic drink per day (if woman); more than two drinks per day (if man)

**Living Environment**

- ☐ Lives on an income of less than \$6000 per year (per individual in the household)
- ☐ Lives alone
- ☐ Is housebound
- ☐ Is concerned about home security

- ☐ Lives in a home with inadequate heating or cooling
- ☐ Does not have a stove and/or refrigerator
- ☐ Is unable or prefers not to spend money on food (<\$25-30 per person spent on food each week)

**Functional Status**

Usually or always needs assistance with (check each that apply):

- ☐ Bathing
- ☐ Dressing
- ☐ Grooming
- ☐ Toileting
- ☐ Eating
- ☐ Walking or moving about
- ☐ Traveling (outside the home)
- ☐ Preparing food
- ☐ Shopping for food or other necessities

**Mental/Cognitive Status**

- ☐ Clinical evidence of impairment, e.g. Folstein <26
- ☐ Clinical evidence of depressive illness, e.g. Beck Depression Inventory >15, Geriatric Depression Scale >5

Patients in whom you have identified one or more major indicator (see pg 2) of poor nutritional status require immediate medical attention; if minor indicators are found, ensure that they are known to a health professional or to the patient's own physician. Patients who display risk factors (see pg 2) of poor nutritional status should be referred to the appropriate health care or social service professional (dietitian, nurse, dentist, case manager, etc.).

These materials developed by the Nutrition Screening Initiative.



Mr. HALL [presiding]. And the Chair thanks you for your time and for your brevity.

The Chair recognizes Mr. Coleman.

**STATEMENT OF HON. RONALD D. COLEMAN, A  
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Mr. COLEMAN. Thank you, Mr. Chairman.

Mr. HALL. Before we do that, let me say, Mr. Coleman, that I totally approve of his bill and I have cosponsored it.

Mr. COLEMAN. I appreciate that very much. I was going to point that out to the rest of the committee members and offer them a grand opportunity to also cosponsor the same legislation. It is H.R. 2305.

By the way, what it does is create the U.S.-Mexico Border Health Commission, and really I am here to testify specifically on that bill, as well as the impact of any health care proposal and what it may have on the U.S.-Mexico border region.

As Chairman of the Border Caucus, I will say to you that the American Journal—the Journal of the American Medical Association most recently had an article which illustrated why we need to be concerned. I have provided a copy of that article for the record as well.

It explored the reasons why Latinos, particularly those of Mexican origin, have the lowest rate of insurance coverage in the Nation. That article demonstrated that if reform is piecemeal, up to 25 percent of Latinos could remain uninsured. Well, those are my constituents and your constituents and a lot of us don't intend to see them being left behind. We have got to keep focused on the twin goals, and I know you are, of universal coverage and cost control, and we have also got to keep the debate positive. I think there are some specific measures that must be taken if we are to truly improve health along the U.S.-Mexico border, and that entire region of the United States, which I happen to think has been neglected for far too long.

I am privileged to represent a border community called El Paso, a city of a half a million people with a sister city just across the river of a million and a half people. That area, that community, shares a lot of things. It shares the air, it shares the water, it shares families, and unfortunately, it shares diseases. They include hepatitis, tuberculosis, measles.

Recently, we discovered the cholera bacteria right across that river. You know, we know that disease doesn't recognize international borders and all of us in El Paso are aware of those problems, especially among the thousands of people that live in what we call colonias in the United States, in El Paso County, in Texas. Estimates run as high as 35,000 people without water or sewage facilities. You know, in this way we are really a community very representative of the U.S.-Mexico border.

And while we don't expect President Clinton's bill to have dealt with every specific need in developing a proposal, as far reaching as the one he has presented, many of us believe we have got to go further if we are going to make a difference on the border region. That is why I think the creation of a U.S.-Mexico Border Health Commission is important.

It was endorsed by the American Medical Association, the medical associations of every Southwestern border State, by public health officials in California and San Diego, El Paso, Tex. I can tell you that I think the time has come for us to understand that we are not going to address the problem of health along the U.S.-Mexico border by only looking in our own backyard. We are going to have to do it on both sides of that border.

I think there is some very interesting proposals that have been made, by the way, by Mexico, with regards to their costs and how we can share those costs together. We don't have to go this alone. Why do we think that we have to only look inward? It is astounding to me that we worry about health care and then even in the legislation itself.

The second issue I wanted to talk about, to suggest we are only going to treat American citizens. Hey, I understand you got to sell a bill. I will buy onto it. We are only going to treat American citizens. But you and I know something different. You know, my hospital treats you whether or not your legal resident status has been established by a due process hearing or not.

If you are having a child and you are having a problem birth, if you have got a leg or an arm cut off, we are going to treat you, right there at my general hospital. We will worry about where you are from and where you were born and whether you have an accent or not, whether you speak the language or not, later.

Well, who pays for that? Well, you and I know that under the current system, the local taxpayers pick that tab up, with no assistance from the Federal Government. Why? Failed immigration policy. I call that a Federal issue, not a local problem. Well, you and I know that the reality is that any legislation that comes forward, many of us know that we are going to continue to treat people in many facilities along that U.S.-Mexico border from Brownsville to San Diego. And so long as we do, there has got to be some mechanism by which my hospitals don't dive into the ground economically, so that they can continue to provide the kind of health care that we all have come to expect in the United States without a diminution because of a lack of finances and a lack of funding from the Federal sources that we know we are going to need if we are going to continue to treat people in the real world.

And, by the way, what is wrong with that? If a child has got tuberculosis, I would much rather us cure that tuberculosis and let that child go back to school. And by the way, the U.S. Supreme Court has ordered that that child is entitled to a free public education in my State and yours. And I would rather us start curing the tuberculosis and let that child back than let that child back in the classroom without curing it to infect other children.

When it comes to communicable diseases, I can tell you right now, let's not worry about the niceties of what we say about a card that we are going to carry around and provide only to American citizens. You and I know that we are going to have to have some funding mechanism to deal with the problems that hospitals are going to see. And I would say to you that while we have been promised Federal funding to address the burden, my staff has been told by representatives of the White House that they already know that the funding will be insufficient to cover the expenses. So we need

to call this what it is so far, it is an unfunded mandate once again to units of local governments and States.

I want to remind you once again of the empty promise we had called SLIAG. You may remember the State Legalization Impact Assistance Grant Program that was made in connection with the Immigration Reform Act of 1986. Six billion dollars was the promise, I remember it. When I voted no on that legislation, I said I did it because I didn't believe it.

I serve on the Appropriations Committee and nobody had asked us for the money. Sure enough, what is it, 8 years later now, we have seen about \$2 billion been requested and expended. That is a shortchange to units of local governments and States, and we ought not to let that happen with a health care plan that we are requesting to believe in. And so I would just say that I hope the committee will agree that H.R. 2305, dealing with U.S.-Mexico Border Health Commission legislation is important, it should be incorporated into any comprehensive health care legislation.

And second, that we will also look at the real way that we are going to begin to fund the problems that many, many health care providers in poorer regions of the United States are going to have to deal with the issue.

Thank you very much for permitting me to testify here this morning.

[The article referred to by Mr. Coleman follows:]



# Insuring Latinos Against the Costs of Illness

R. Sardiaga Valdez, PhD; Hal Morgenstern, PhD; E. Richard Brown, PhD; Roberta Wym, MPH; Chao Wang, PhD; William Cumberland, PhD

**Objective.**—To examine the determinants of health insurance coverage for Latinos in the United States and how different targeted strategies for health care reform differentially affect the country's major ethnic groups, focusing on the implications for the Latino population.

**Design.**—Data from the 1980 and 1990 Current Population Surveys were used to compare the insurance status of nonelderly (<65 years) Latinos with the Anglo (non-Hispanic white), black, and Asian and other populations by estimating the attributable fraction for selected covariates. The effects of health care reform strategies on the coverage of the major ethnic groups were simulated from these data.

**Main Outcome Measures.**—Percentage uninsured, percentage insured by Medicaid, and attributable fraction for covariates.

**Results.**—Latinos have the worst health insurance coverage of any ethnic group in the country. Approximately 39% of Latinos are uninsured compared with 13.8% for the Anglo and 24% for the black population. Providing coverage to all the poor could reduce the uninsured rate for Anglos by about 23%, whereas the reduction among Latinos could be about 37% and among blacks about 42%. Similar reductions could be achieved by covering all workers and their minor dependents. Regardless of the approach to reform, however, Latinos would remain with high absolute rates of uninsured.

**Conclusions.**—Differences in Medicaid eligibility, labor force characteristics, and family composition between Latinos and other ethnic groups suggest that policy initiatives may affect Latinos differently. Targeted strategies, such as employer mandates, "pay-or-play" programs, or Medicaid expansions, can improve coverage, but many Latinos could still remain uninsured.

(*JAMA*. 1993;269:299-304)

LATINOS, especially Mexican Americans, have the lowest level of medical and mental health care utilization in the country.<sup>1-3</sup> While it is not clear why this situation exists, issues of access to care are at the center of the debate. Health insurance coverage and affordability are major determinants of access to care.<sup>4</sup>

Among all ethnic groups in the

United States, Latinos are least likely to have insurance coverage against losses due to illness.<sup>5</sup> The Latino population deserves special consideration because it is often assumed by policymakers that policies devised with poor black communities in mind will equally well serve other poor populations. But persistent poverty among Latinos exists despite high rates of labor force participation and family formation. Therefore, this article examines the magnitude and the potential reasons for lower health insurance coverage among Latino populations. It also illustrates the impacts that public policies aimed at reducing the proportion of uninsured Americans may have on the Latino population.

Latinos, particularly Mexican Americans, are uninsured because their pri-

mary employment is in the lower skilled and paid sectors of the economy, which are less likely to provide insurance coverage as a benefit. Therefore, Latino communities appear particularly vulnerable to the weaknesses in the current system of financing medical care. Furthermore, a large proportion of Latinos live in states such as Texas and Florida that severely restrict eligibility for Medicaid services. Restricted eligibility standards increase the number of uninsured in a state.<sup>6</sup> But even in states with more generous eligibility standards, such as California and New York, few providers participate in Medicaid programs because of low payment schedules and excessive reimbursement delays.<sup>4,7</sup> Thus, the categorical nature of the Medicaid programs, which serve only a fraction of the nation's poor, and the inadequate medical resources available through these programs further reduce access for Latinos.

Finally, the extent of health insurance coverage among those labeled as insured is not well understood. Recent trends in health insurance plan design, characterized by higher deductibles and coinsurance,<sup>8,9</sup> suggest that even among the insured the net personal expense of seeking medical care has risen. Thus, given the relatively low family income among Latinos, even the insured face higher medical care costs.

This article illustrates that health insurance coverage for Latinos varies considerably, reflecting geographic differences in state Medicaid policies and labor markets. Strategies to reduce the number of uninsured that are aimed at the working poor and their dependents would benefit the Latino community greatly, but would still leave sizable numbers uninsured. Employer-mandated strategies, however, pose numerous serious economic risks for Latinos, including potential job losses or dislocations.<sup>10</sup>

From the Departments of Health Services (Dr Valdez and Ms Wym), Epidemiology (Dr Morgenstern), Community Health Sciences (Dr Brown), and Biostatistics (Drs Wang and Cumberland), UCLA School of Public Health, Los Angeles, Calif; and the UCLA/RAND Center for Health Policy Studies (Dr Valdez), Santa Monica, Calif.

The opinions expressed herein are those of the authors & do not necessarily reflect the opinions of the sponsors, UCLA, or RAND.

Reprint requests to Department of Health Services, UCLA School of Public Health, Los Angeles, CA 90024-1772 (Dr Valdez).



## METHODS

We analyzed data from the 1980 and 1990 March Current Population Surveys (CPS), which includes socioeconomic information collected by the US Bureau of the Census. The CPS provides information about work experience, income, family structure, migration, health insurance coverage, and other characteristics.

The March CPS sample is a national probability sample drawn so that estimates that are properly weighted can be generalized to the US population and the populations of large states such as California, Texas, Florida, and New York.

Respondents to the CPS were interviewed by trained census employees, but standard Spanish translations of the survey were not used. Instead, Spanish-speaking interviewers independently translated questions and responses, and non-Spanish speakers relied on translators, if one could be found. (This is standard procedure for many of our national surveys; however, these survey procedures are believed to result in an undercount of the number of uninsured Latinos.) Surveyors collected information on health insurance coverage for each household member during the preceding year.

The health insurance coverage questions ask whether each person was covered by a group health insurance plan obtained through employment, individual purchase, CHAMPUS or military medical services, Medicare, or Medicaid. Persons covered by any of these sources at any time during the previous year are categorized as insured. The remaining population—those with no third-party coverage during the entire year—are described as the uninsured. Because people in our insured category include those with coverage for only part of a given year, prevalence estimates for the uninsured population are conservative.

New questions added to the CPS insurance battery in 1988 asking general, rather than specific, questions about children's insurance coverage were not used to compute the 1990 estimates in this article. Ignoring the new questions permits the calculation of insurance coverage status compatible with earlier estimates. When one includes some or all information from these new variables, the 1990 estimates of the uninsured nationally decrease by varying levels depending on how the new information about children is treated.<sup>1,2</sup> Estimates for Latino children do not appear to be sensitive to these questions but responses for other children suggest fewer uninsured among that group. Therefore, the insurance coverage estimates of the total nonelderly populations may

overestimate the number of uninsured in some groups. These new questions, however, do not affect estimates among the working-age population.

Despite the reliance on self-reporting of health insurance coverage, respondents provide fairly accurate information about whether they are insured, whether the insurance is public or private, and its source.<sup>11</sup> But respondents are less accurate in describing the scope of benefits for themselves and their dependents.<sup>12</sup> In general, respondents sometimes think they or their dependents are covered when they are not.

Using information about family relationships within households, we constructed units of observation that are commonly eligible for health insurance coverage. These "insurable units" were classified into four types: (1) married couples with minor children or youth in college, (2) single parents with children or youth in college, (3) married couples without children, and (4) single adults.

These units reflect the customary patterns of eligibility under most private health insurance plans. Thus, some households contain more than one insurable unit. For example, a household composed of a married couple and their three children aged 25, 17, and 8 years could have two insurable units: one unit composed of the married couple and their dependent children and the other unit composed of the 25-year-old. We used information about individuals' age, primary work-related activity, and family relationship to assign them to an insurable unit.

Our comparisons focus on differences between Latinos and other ethnic groups in the United States as a whole and in states with high concentrations of Latinos. Respondents were categorized on the basis of self-reported ethnicity and interviewer-identified race. We categorized Latinos as individuals of any race who identified themselves as Hispanics of American origin (eg, Mexican, Puerto Rican, Cuban, or Central or South American). Hispanics of European origin and other non-Latino white individuals were classified as Anglo (a general ethnic identification commonly used in the American Southwest), non-Latino blacks or African Americans were classified as black, and non-Latino Asians and all other groups were identified as "Asian and other."

## Analysis

To understand what factors contribute to the difference in health insurance coverage between Latinos and Anglos, we applied a stratified analysis (frequently used in epidemiology<sup>13</sup>) and expressed the unadjusted association be-

tween ethnicity and lack of insurance coverage as the crude relative risk (crude ratio [CR]): the proportion of Latinos who are uninsured divided by the proportion of Anglos who are uninsured. The crude attributable fraction (AF) in the Latino ("exposed") population, estimated by the quantity  $(CR-1)/CR$ , is the proportion of uninsured Latinos who would have been insured had they been Anglo. The difference between the actual number of uninsured Latinos and the expected number had they been Anglo is the attributable number (AN)—ie, the excess number of uninsured Latinos who would have been insured had they been Anglo, which is estimated by multiplying AF by the total number of uninsured Latinos in the population.

The primary objective of the stratified analyses was to estimate the proportion of the attributable number that is due specifically to differences in the distribution of one or more other variables (covariates) that are known to affect health insurance coverage. We refer to this proportion as the attributable fraction for covariates (AFC). Using this measure, therefore, we are able to quantify how much of the difference in insurance coverage between Latinos and Anglos is explained by ethnic differences in selected covariates. For example, we were able to determine how much of the Latino-Anglo difference in insurance coverage is due to ethnic differences in economic factors and/or family structure.

The AFC is estimated by comparing the crude AF with the AF standardized (adjusted) for covariates. The standardized AF is estimated by the quantity  $(SR-1)/SR$ , where SR (the standardized ratio) is the ratio of uninsured rates, comparing Latinos with Anglos, standardized to the covariate distribution of the total Latino population. Thus, the SR reflects the magnitude of the association between ethnicity and lack of insurance coverage, controlling for covariates. (In epidemiology, the SR is often called the standardized morbidity or mortality ratio; it is equivalent to the estimated ratio of observed to expected numbers of uninsured Latinos.) Thus, substituting the above quantities for the crude and standardized attributable fractions, we have the following formula:

$$AFC = \frac{\frac{CR-1}{CR} - \frac{SR-1}{SR}}{\frac{CR-1}{CR} - \frac{SR-1}{SR}}$$

To estimate a standard error for the AFC, a Taylor series was used to approximate its variance as a simple com-

Table 1.—Proportion of Uninsured Nondaily (<65-Year-Old) Residents in the United States by Year and Ethnicity\*

Ethnicity†	1979		1980		Change	
	No. (x1000)	%	No. (x1000)	%	No. (x1000)	%
All United States	28 703	14.8	37 739	17.5	9036	31.5
Latino	2860	25.7	7177	38.0	4317	150.9
Mexican	2119	27.8	5301	41.8	3182	150.2
Puerto Rican	291	18.5	463	22.6	172	59.1
Cuban	168	22.1	182	22.1	27	16.4
Others	285	26.9	1221	44.3	936	326.4
Anglo	19 716	12.7	22 281	13.6	2565	13.0
Black	5236	22.7	8584	24.0	3348	25.7
Asian and other	891	22.1	1605	21.8	804	90.2

\*Source of data was March 1980 and 1980 Current Population Surveys.

†Latino indicates Hispanics of any race from the Western hemisphere; Anglo, the non-Hispanic white population and Hispanics of European country of origin; Black, the non-Hispanic black population or African Americans; and Asian and other, the remainder of the non-Hispanic population, which is composed primarily of peoples of Asian heritage.

‡Other Latinos include Central and South Americans.

bination of variances and covariances of its components. In sampling terminology, this is often referred to as linearization. A similar procedure was done to approximate the variance of the attributable fraction (AF). Adjustments to the variance estimates for clustering were not done because the CPS does not include the necessary variables to define the clusters. (Thus, the 95% confidence intervals shown in Table 5 may be slightly conservative [too narrow].)

By multiplying the AFC by the total attributable number (AN), we estimate the number of excess uninsured Latinos attributable to ethnic differences in the covariates (ANC)—i.e., the number of uninsured Latinos who would have been insured if they had the same covariate distribution as Anglos.

An alternative method for estimating AF and AFC is to use a model-fitting technique, such as logistic regression.<sup>14,15</sup> But this approach requires additional assumptions about the mathematical relationship between predictors and outcome, and it is more tedious to apply, especially with data collected in a complex survey.

The AFC may be computed for various sets of covariates by stratifying simultaneously all covariates in each set. In this way, we can explain the Latino-Anglo difference in insurance coverage in terms of multiple factors. We examined the role of age, sex, education, family income (relative to the poverty level), family size, employment status (full-time/full-year, full-time/part-year, part-time, or unemployed), type of industry, type of occupation, firm size (where employed), insurable unit size and type, and state of residence in attempting to explain the Latino-Anglo difference.

Because Latinos are regionally concentrated, we decided to focus our stratified analyses on information from the

nine states with the largest Latino populations. Eighty-five percent of the entire Latino population lives in these states. Concentrating our analysis on these nine states, rather than using the entire nation, permits a more efficient within-state comparison of differences between Latinos and Anglos.

Limitations in the CPS data preclude us from examining other factors that may play a role in health insurance coverage. In particular, the CPS contains no information about health status, the extent or nature of health insurance coverage, medical care expenses, sources of care, or other employer-related information such as whether insurance was offered or level of shared plan expenses.

In order to determine how health insurance coverage would change under different strategies, assuming these factors remained constant, we used information about the employment and insurable unit characteristics associated with individuals to perform a series of simple projections. These projections provide an initial basis for understanding differential impacts of public policies on various ethnic groups. Little serious analysis of the distributional effects of targeted policy approaches exists despite decision makers' and policy analysts' preference for such strategies.

We examined the following general strategies representing a broad range of approaches:

1. Provide coverage for all poor individuals (individuals with family income below the federal poverty level).
2. Provide coverage for all minors.
3. Provide coverage for all full-time workers (those who work 35 hours or more for at least 50 weeks a year).
4. Provide coverage for all full-time workers and their children (i.e., all their minor dependents).

5. Provide coverage for full-time and part-time workers (i.e., all active employees).

6. Provide coverage for full-time and part-time workers and their children (active employees and their dependent children).

7. Provide coverage for all poor individuals and all full-time workers (all individuals below the poverty level plus all fully employed persons).

Other strategies and mixes could be examined, but these provide an initial examination of the broad range of strategies that are generally being debated across the country. For example, Medicaid expansion strategies call for covering the entire population of individuals below the poverty line. Employer mandate strategies specify the coverage of those in the work force with some specific number of hours of work per week. Some of these mandated proposals include the coverage of dependents as well as the employed individual. Many "pay-or-play" proposals include mandated employer coverage and Medicaid expansion.

For each strategy, uninsured individuals with particular personal or insurable unit characteristics that meet the coverage criteria were reassigned to an insured status, and the overall impact on ethnic group health insurance coverage was assessed. For example, one strategy could call for developing a national health plan that provides health insurance coverage for all children under 18 years of age. If we reassign uninsured children to the insured category, what impact would this have on Latinos and other ethnic groups?

## RESULTS

In 1989, 39% of Latinos under 65 years of age—7.2 million persons—were uninsured for the entire year (Table 1). This rate is about three times higher than the rate experienced by Anglos (i.e., the non-Latino white population) and almost twice the rate experienced by blacks. In 1989, there were more uninsured Latinos than uninsured blacks (6.5 million) in America. (Our estimates using the additional CPS child questions indicate that 38% of Latinos, 13% of Anglos, 23% of blacks, and 21% of Asians and others were uninsured in 1989.)

There is substantial variability in insurance coverage among Latinos. For example, Puerto Ricans and Cubans experience nearly half the uninsured rate experienced by Mexican Americans and Central and South Americans. The dramatic estimate of Latino uninsured reflects the increasing numbers of uninsured Mexicans and Central and South

Table 2.—Health Insurance Coverage in the Nine States With the Largest Latino Nonselderly Populations in 1989\*

State	Total (x1000)	Proportion of Nonselderly Latino Population, %		
		Uninsured	Medicaid	Other Insurance
All United States	18 422	38.0	11.8	49.2
California	6944	43.7	11.0	46.3
Texas	3980	47.8	7.8	44.8
New York	1727	31.0	28.2	42.8
Florida	1331	36.5	8.7	56.8
Illinois	828	22.9	18.0	66.2
New Jersey	533	28.1	10.5	61.5
Connecticut	122	13.5	11.5	73.0
Washington	106	23.3	20.3	56.4
Michigan	100	12.5	25.5	62.1

\*Source of data was March 1990 Current Population Survey.

†Other insured category includes group and individual coverage, as well as some Medicare coverage.

Table 3.—Proportion of Full-time Work Force Without Health Insurance in 1989 by Ethnicity, Gender, and Selected Industries\*

Industry	Proportion Uninsured, %			
	Latino	Anglo	Black	Asian and Other
	Men			
Agriculture	55.2	23.2	82.2	37.8
Construction	50.1	25.1	42.0	28.8
Durables	26.9	6.7	14.2	12.4
Retail	48.9	18.0	36.3	33.5
Personal services	50.2	17.5	37.8	29.3
Professional	21.4	7.7	15.0	11.0
Women				
Agriculture	66.3	15.6	49.7	47.5
Durables	20.9	7.3	9.3	11.1
Retail	40.5	10.3	28.3	23.4
Personal services	56.2	18.0	44.0	27.7
Professional	19.0	7.4	13.6	15.2

\*Source of data was March 1990 Current Population Survey.

Americans and the growth in the uninsured rate. In the last 10 years, the number of uninsured Mexicans increased by 150% and the number of uninsured Central and South Americans increased by 328%.

Latinos living in the Southwest and South are more likely to be uninsured than Latinos living in other parts of the country. (These regions of the country tend to have higher rates of uninsured among all populations compared with other regions.) The number of uninsured Latinos increased by 168% in the Southwest, by 156% in the South, by 108% in the Northeast, and by 64% in the Midwest during the 1980s.

Examining the insurance coverage of those nine states with the largest Latino populations suggests that state differences in Medicaid coverage greatly affect the proportion of Latinos who are left uninsured (Table 2). Some states provide a substantial proportion of coverage through their Medicaid programs, such as New York (26.2%), Michigan

(25.5%), and Washington (20.3%). Other states with more restrictive eligibility standards provide a relatively small share of insurance coverage, such as Texas (7.8%) and Florida (6.7%).

Because most individuals obtain their health insurance coverage through employment, either directly or indirectly through a spouse or parent, we examined the labor force participation and characteristics of Latinos (Table 3). The national distribution of full-time workers across major industry categories indicates that Latinos are distributed across jobs in roughly the same proportion as the Anglo work force, except with slightly higher participation in agriculture, sales, and personal services. These industries tend to provide health benefits sparingly. This rather similar distribution across industries, however, masks ethnic group differences in occupations within industries: Latinos are far more likely than Anglos to be uninsured across all industries by a factor of two to five times. For example, among

men, 60% of Latinos and 25% of Anglos in construction are uninsured; 35% of Latinos and 7.5% of Anglos in the non-durable manufacturing industries are uninsured. Similar relationships are found among the female work force.

Employees who work for small firms are less likely to receive employer-sponsored health benefits. Latinos, particularly those in the South and Southwest, are more likely than Anglos to work for small employers (firms with fewer than 25 employees) and to be paid on an hourly basis. For example, 74% of Latinos and 50% of Anglos in the Southwest are paid on an hourly basis. These labor force differences are most acute in California,<sup>14</sup> where 30% of full-time Latino employees work in firms with fewer than 25 employees, compared with 18% of Anglos. The higher concentration of Latino workers in relatively low-coverage industries and smaller firms reduces their likelihood of receiving health benefits.

To determine what factors account for the difference in health insurance coverage between Latinos and Anglos, we estimated the AFC in the Latino population and the AFC. In 1989, there were 6.2 million uninsured nonselderly Latinos living in nine states. Of this number, 57.8% (the estimated AFC) would have been insured if they had been Anglo (Table 4). This fraction represents about 4.2 million excess uninsured Latinos—the estimated attributable number (AN).

By stratifying for one or more covariates, we estimated the proportion (AFC) of the Latino-Anglo difference in insurance coverage that was due to ethnic differences in the covariate distribution. The covariates that explained individually the largest portions of this difference were family income (AFC, 23.0%), education (AFC, 12.2%), occupation (AFC, 6.6%), and state of residence (AFC, 6.5%) (Table 4). Relatively little of the Latino-Anglo difference in insurance coverage was explained by ethnic differences in age, sex, characteristics of the insurable unit, or employment factors other than income. Collectively, the AFC for the combination of family income, education, and occupation was 35.7%. That is, of the 4.2 million excess uninsured Latinos in 1989, a total of 35.7%—or about 1.5 million Latinos—would have been insured if they had the same distribution of income, education, and occupation as did Anglos. No other combination of the covariates in Table 4 explained a significant degree of the Latino-Anglo difference in insurance coverage. Thus, more than 60% of this difference appears to be due to ethnic differences in other factors not included in these analyses.



Table 4.—Attributable Fraction for Selected Covariates (AFC) Explaining the Latino-Anglo Difference in Health Insurance Coverage in Nine US States, 1989

Covariate(s) (No. of Strata)	SR*	AFC,† %	95% CI (AFC), %	ANCS (x1000)
None (1)	3.10	67.8	66.6-69.0	4176
Age (7)	2.94	2.5	2.1-3.0	108
Sex (2)	3.10	0.05	0.0-0.1	2
Education (4)	2.47	12.2	10.7-13.8	511
Family income (4)	1.83	33.0	30.8-35.3	1379
Employment status (4)	2.97	2.1	1.7-2.5	88
Industry (7)	2.95	2.8	2.0-3.0	104
Occupation (6)	2.72	5.6	5.3-7.4	276
Firm size (6)	2.95	2.4	1.9-2.8	99
Type of insurable unit (4)	2.86	4.0	3.4-4.5	169
Size of insurable unit (5)	3.20	-1.5	-1.9-1.1	...§
State of residence (9)	2.73	5.5	5.3-7.6	270
Occupation and education (24)	2.38	14.4	12.6-16.2	601
Occupation and family income (24)	1.81	34.1	31.7-38.5	1423
Family income and education (16)	1.78	35.2	32.4-38.1	1471
Family income and education and occupation (36)	1.77	35.7	32.8-38.6	1481

\*The standardized ratio (SR) is the ratio of uninsured rates, comparing Latinos with Anglos, standardized to the coverage distribution of Latinos. When there are no covariates, the value shown is the crude ratio.

†The AFC is the proportion of the Latino-Anglo difference in insurance coverage that is due to ethnic differences in the distribution of covariates. When there are no covariates, the value shown is the attributable fraction in the Latino population. CI indicates confidence interval.

‡The attributable number for covariates (ANC) is the number of excess uninsured Latinos that is due to ethnic differences in the distribution of covariates. When there are no covariates, the value shown is the total attributable number.

§The ANC is not estimated when the AFC is negative, because a negative AFC means that fewer (not more) Latinos would have been insured if they had the same covariate distribution as Anglos. Thus, ethnic differences in this covariate do not explain the excess lack of insurance among Latinos.

Differences in Medicaid eligibility, labor force characteristics, and insurable unit composition between Latinos and other ethnic groups suggest that public policy initiatives may affect Latinos differently. We examined simple simulations to determine if this was the case (Table 5). Efforts to expand Medicaid to cover all poor people (ie, by dropping categorical eligibility standards) or other initiatives to cover all the poor, for example, would be expected to reduce the proportion of uninsured Americans by 29%. This impact, however, would be greater among populations with large proportions of their populations living in poverty, such as Latinos (37% reduction) and blacks (42% reduction).

Efforts to ensure coverage of the working population (ie, full- and part-time workers) such as employer mandates would produce reductions of 22% overall, with similar reduction levels in all ethnic groups. Efforts that combine mechanisms to cover the full-time work force and the poor, such as pay-or-play proposals, could be expected to reduce the overall national rate by 46%, the Latino rate by 54%, and the black rate by 56%.

No matter which strategy we choose to undertake, Latinos may still face major health financing difficulties. For example, applying the strategy that would cover all poor people in the United States could result in a decline in the Latino uninsured rate from 39% to 24.6%; al-

ternatively, applying a strategy that provides health benefits to all workers and their minor dependents would result in a decline of the uninsured rate among Latinos to 10.8%. None of the seven strategies we examined reduced the uninsured rate below 10% because some element of the population was not specified in the strategy.

#### COMMENT

The dramatic increase in the number of uninsured among the Mexican and Central/South American populations reflects several social and economic trends affecting the United States. Two trends deserve special consideration: Latino population growth and the restructuring of the economy.

The rapid growth of the Latino population reflects both increased immigration and higher fertility rates than are found in other groups. Many Latino immigrants, especially the Mexican and Central American populations, have settled in the South and Southwest, regions in which state eligibility for Medicaid remains severely limited.<sup>17</sup>

Historically, immigrants occupy the lower end of the occupational distribution. Because of limited education and the lack of job skills required in the United States, Mexican and Central American immigrants are often employed in low-paying jobs that do not include health insurance as a benefit of

employment. Many native Latinos also work in low-paying jobs that lack benefits such as health insurance.<sup>18,19</sup>

Higher-than-average fertility levels among both native and immigrant segments of the Latino population result in a larger share of dependents. Latinos and Mexican Americans in particular have a greater number of dependents per worker than do Anglos or blacks. A large share of the dependents are children and women who are not working for wages. Therefore, proposals that only address coverage for workers and exclude benefits for family members provide limited protection for Latinos against the costs of illness.

The restructuring of the economy, however, may reduce the types and amounts of compensation made to less skilled workers. Increasingly, the economy has seen job growth in high- and low-skilled occupations. During the 1980s the real wages of low-skilled workers stagnated or declined while higher-skilled workers prospered.<sup>19</sup> Similarly, benefits, including health insurance coverage, have shrunk for most workers. Given that Latinos are disproportionately employed in small firms, in low-wage jobs, and in industries that historically provide few benefits, perhaps it is not surprising that Latinos lack health insurance coverage under our voluntary employment-based approach.

As our projections indicate, incremental efforts to change the voluntary employment-based health insurance scheme could still leave many Latinos uninsured. Furthermore, the likely economic disruptions that some of these strategies could produce would further negatively affect the various Latino communities.

Strategies mandating employers to provide health insurance coverage to their employees pose several major concerns for Latinos. First, such strategies threaten jobs available to this community. To the extent that employers face increased costs of labor, some may be forced to lay off workers, keep wages low, or go out of business. Given the relatively high concentration of Latinos working for small business and operating small businesses, such strategies pose considerable concern and threats. Second, mandates, depending on how they are specified, could leave out large segments of the Latino population. Covering only those in the work-force would leave many Latinos, especially children, without coverage. Third, low-wage jobs could see further declines in real wages to pay for the mandated fringe benefits. These potential effects would further reduce financial resources available in these communities to pay for increasingly more expensive medical care.



Table 5.—Projected Percentage Reduction in the Uninsured Rates Under Different Strategies for Covering the Uninsured by Ethnicity\*

Strategy	Total United States	Latino	Anglo	Black	Asian and Other
% Uninsured in 1989	17.5	39.0	13.8	24.0	21.8
Projected % Reduction					
Poor (<1.0 PI)	29	37	23	42	25
All children (<18 y)	34	36	33	37	33
Full-time workers	18	21	18	16	17
Full-time workers and minor dependents	34	39	34	32	30
Full-time/part-time workers	22	23	23	20	20
Full-time/part-time workers and dependents	41	44	41	38	36
Full-time workers and poor	46	54	40	56	40

\*Source of data was March 1990 Current Population Survey. PI indicates Poverty Index.

The number of uninsured Latinos in the United States could be dramatically reduced if Medicaid eligibility were not categorically defined and Medicaid were available to serve all of the poor. The proportion of the uninsured in the states with the four largest Latino populations (accounting for about 78% of the uninsured Latinos) would dramatically decline. Efforts directed at California, Texas, New York, and Florida to reduce the proportion of uninsured residents could greatly affect the proportion of Latinos who go without health insurance nationally. Expanding Medicaid eligibility under the current federal-state financing arrangements, however, could create severe state budget crises. But expansion of a program in which few providers wish to participate would not alleviate the fundamental problems of access to medical care faced by the Latino population.

Other alternatives include a "pay-or-play" approach that would provide coverage through job-based benefits or a public program and universal national or state health insurance. The public

program in a pay-or-play system would cover primarily the lower-income population, thus running the risk of political isolation and vulnerability to budget cuts. These budget constraints could lead to low provider reimbursement rates, as in the current Medicaid program, which would create access barriers for persons enrolled in the program. A universal public program could avoid that dilemma by giving all sectors of society a common stake in controlling health spending and increasing access to quality care.

No matter which strategy we undertake, Latinos may still face major health care access difficulties. Thus, we must look beyond simply "the financing" to consider basic reform of this nation's medical care system. Recent work in Los Angeles County, California, demonstrates the failure of the current system to provide basic primary care to our communities.<sup>28</sup> We see rates of hospitalizations for conditions that we know how to inexpensively treat, prevent, and control in a physician's office that are two to three times the expected rate.

These hospitalizations are very costly for the individual patients, their families, and society.<sup>29</sup>

Ensuring adequate medical care services to the Latino community requires attention to both the financing mechanisms and the structure of the medical care system. Even Latinos with health insurance cannot find an adequate supply of providers in their communities. Many physicians serving Latino communities immigrated to the United States during the mid 1960s and early 1970s. Those physicians are near retirement, but US medical schools have not produced adequate numbers of native Latino physicians to replace them. Few providers understand the social or cultural issues important to providing high-quality medical care in Latino communities. Speaking some Spanish is a necessary but insufficient prerequisite.

A redirection to consumer-sponsored comprehensive prepaid health plans would greatly serve Latino communities. Such efforts, exemplified on a small scale by the Office of Economic Opportunity's neighborhood health centers and, on a larger scale, by such plans as the Group Health Cooperative of Puget Sound, offer Latino neighborhoods multiple benefits, economic opportunity, job training and education, decision-making power, and, of course, primary medical care. Current debates about health care reform must take into account the structural problems we face in providing medical care, especially in Latino communities.

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Mr. PALLONE [presiding]. Thank you. Thanks a lot, we will take that into consideration.

Congressman Traficant.

**STATEMENT OF HON. JAMES A. TRAFICANT, JR., A  
REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO**

Mr. TRAFICANT. Thank you. I want to thank the committee for having me in here to testify. I have three specific issues. Two of them are bills I have submitted. The last is an amendment because you can't have a bill when a card doesn't exist at this point.

The first one deals with the Council on Graduate Medical Education who have told us repeatedly that increasing specialization in the health care industry forces costs up, and the medical schools have been dealing mostly and primarily trying to deal with this specialization, and most doctors and most professionals seek this specialization.

H.R. 3220 will shift the number of health professionals hopefully into primary care service delivery systems that will save an awful lot of money and they are drastically needed in our country. So the first part basically does this, of H.R. 3220. Medical schools that receive Federal grant or contract money must agree to emphasize, incorporate in their curriculum and their delivery system, primary care training and emphasize such and encourage such to produce more primary care physicians. It doesn't stop specialization.

Second, part of it is basically this, American citizens and legal residents should be given priority through American medical schools. I agree wholeheartedly what Mr. Coleman had stated. He is exactly right.

When we talk about our kids having to go to Grenada to get a medical degree, it astounds me. In the Traficant bill, second part of H.R. 3220 says if there is a slot open and there is an American student that qualifies for it, that American student gets the preference.

The second bill deals with lower back pain. I don't want to give you anymore of that. H.R. 2079, it has a very funny name to it called the arachnoiditis. Very controversial now. It is sort of taking the pattern on of the breast implants and that whole controversy over the years, people denying the problem, admitting the problem, studying the problem.

Arachnoiditis is basically this, it is an inflammation of the lower back, the subarachnoid area, basically caused in these myelograms where they inject these dyes. There is two types of dyes, oil-based dyes, water-based dyes. And the problem is after they remove the dyes after the test, there is a lingering residue that is being carefully now stated as a common problem and a contributor to permanent back pain. And they are saying this is one of the most costly health-related problems that we have.

The Traficant bill would, in fact, in this position call for a study of all of those afflicted with it, but it would ban the oil-based and water-based dyes used in these myelograms. It would not stop, though, the procedures, and it would call for a study on them and to specifically address itself to those individuals who suffer from it.

Just let me say this. Eighty million Americans who suffer chronic back pain, four out of those five cases could have been prevented.

Many of our costs that we deal with in the Federal Government from lower back pain, and these cases are permanent to our coffers. These individuals are lost from work. The average loss of work, by the way, is about 5 days a week, \$55 billion a year from back pain.

I am asking you to take a good look at these dyes. Pantopaque is the oil-based. You have Amipaque, Omipaque, and Isovium as the water-based dyes, and I am asking that we would look at that and ban them and to study other methods and methodologies to assess that need to study that lower back area.

Finally, we talked about the card. It is not a bill because there is no card. And I am saying rather than have two or three different cards, in the form of an amendment it basically says this, that the Social Security card and the Health Security Act be rolled into one. You have one number, your Social Security card number. And that amendment provides for protections with computer programming and blocking that would retain the confidentiality of the use of that card. So we wouldn't have people with a number of different cards and it also calls for a study in there to see how that database can be affected by the card holder themselves as they are responsible with their own automatic teller machine cards, et cetera.

So it is not a real reinvention of the wheel, but here is what the third one says, Mr. Chairman. There would just be one card. We would get a grip on what the social security card is all about and all the people there, who is living, who is not, what mistakes we have. And that social security number also becomes your health security number. It is one card, both of those phase into that one particular card. The new card would be issued and the identification from that would be manifest in that process.

It also calls for a study how we can through our super technology, the information highway, prevent the access from people who would be eavesdropping for other information. Someone might want to know, for example, if Mr. Regula has a family history tree, has a heart problem, heart condition when they are hiring. Say, well maybe we will stay away from Ralph because his family had three or four brothers and they are known for heart disease.

I think that is clearly unconstitutional, to allow that kind of tapping. And although we don't have the technology right now, it puts in place, at least, and calls for a study of that technology and a review to, in fact, prevent that from happening and protect the confidentiality of the privacy of patients.

I know the arachnoiditis is very controversial at this particular point, but so were breast implants. I am asking you look at those two bills and that amendment. They make a lot of sense.

The only last thing I will say, I want to be very careful, everybody ends up with health insurance and no one ends up with a job. And finally, I absolutely want to place upon the record here, whatever the health insurance program is for the Nation, each and every one of us have the same health insurance that our constituents carry around and the same card and the same program for service.

I thank you for your time.

Mr. PALLONE. Thank you, Jim.

[The prepared statement of Mr. Traficant follows:]



JAMES A. TRAFICANT, JR.  
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CHAIRMAN SUBCOMMITTEE ON  
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ABUSE AND CONTROL

**Congress of the United States**  
**House of Representatives**  
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**STATEMENT OF THE HONORABLE**  
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Mr. Chairman and members of the Committee, thank you for the opportunity to testify on health care reform and to offer my recommendations in legislative form. While recent reports suggest health care inflation is the lowest it's been in a decade, medical spending is expected to top \$1 trillion dollars in 1994 - with or without the enactment of a national health care plan.

I believe wholeheartedly that every American should have access to affordable as well as responsible health care. My top concern in the consideration of a comprehensive health care reform package is the funding mechanism. The bottom line is, who's going to pay for it? The Department of Labor recently reported that, for the average American worker making \$12.68 an hour, an employer has to come up with \$5.20 in benefits. That's a 41 percent expenditure in addition to the average worker's pay or \$15,246 a year according to U.S. Chamber of Commerce statistics. This trend is even higher for the government and big business. I caution Members of Congress to be careful that we don't win the battle for health care and lose jobs in the process.

I believe that any health plan considered by Congress should address the following:

1. Coverage or incentive for the insurance industry to cover the nation's 37 million uninsured and underinsured.
2. Medicare waste and fraud must be eradicated. Fraud may



account for \$75 billion of America's annual health care expenditures.

3. Tort reform. Physicians must cease the practice of providing unnecessary care which adds an additional \$21 billion to the U.S. health care bill every year.

4. An emphasis on preventative care. The excessive costs of catastrophic care can be greatly deflated through early testing, nutrition counselling and education, prenatal care, etc.

Finally, I strongly believe a comprehensive health care reform package should firmly address and provide for three additional provisions. At this time, I would appreciate the opportunity to offer my legislation which speaks to these issues.

First, it's a well-known fact that shifting the emphasis in the physician workforce from specialists to generalists will improve access to health care and cut costs. In fact, the Council on Graduate Medical Education (COGME) under the Department of Health and Human Services has issued an extensive report supporting this fact called, "Improving Access to Health Care Through Physician Workforce Reform: Directions for the 21st Century." America is in need of more primary care physicians. As a result, I have introduced H.R. 3220, the "Health Professions Education Availability Act of 1993," to emphasize training in primary care education and to encourage students to enter a field in primary care.

At this time, I would like to summarize COGME's findings on this issue. First, the growing shortage of practicing generalists (i.e. family physicians, general internists, and general pediatricians) will be greatly aggravated by the growing percentage of medical school graduates who plan to specialize. The expansion of managed care and provision of universal care will only further increase the demand for generalist physicians. Second, increasing specialization in U.S. health

care escalates health care costs, results in fragmentation of services, and increases the discrepancy between numbers of rural and urban physicians. Third, a rational health care system must be based upon an infrastructure consisting of a majority of generalist physicians trained to provide quality primary care and an appropriate mix of other specialists to meet health care needs. Today, other specialists provide a significant amount of primary care. However, physicians who are trained, practice, and receive continuing education in the generalist disciplines provide more cost-effective care than nonprimary care specialists.

In its first report in 1988, COGME recommended increased numbers of physicians in family practice and general internal medicine to assist in meeting the problems of access to primary care services. However, interest by medical school graduates is rapidly increasing in procedurally oriented specialties, and similarly, interest in primary care is declining dramatically among U.S. medical students. Should these current trends continue we can conclude that primary care services will increasingly be provided by specialists who have had little or no education for primary care. Moreover, primary care provided by specialists can be expected to cost more. And finally, while an overall increase in the total physician-to-population ratio would further hinder efforts to reduce costs, an oversupply of specialists would be more costly than would an oversupply of generalists.

The truth is, the medical education system must respond today, to the nation's health care and physician workforce needs in the 21st century. These include the need for more minority and generalist physicians, more primary care research, and increased access to primary care, particularly in underserved rural and urban communities. Changes in the institutional mission, goals, admissions policies and curriculum are necessary to respond to these needs. My bill, H.R. 3220, does not increase the overall medical student population, rather, it directs

health professions schools respond to the need for more minority and generalist physicians by shifting the current trends in the physician workforce.

Specifically, under H.R. 3220, a grant or contract to a health professions school can only be awarded if the school agrees to emphasize training in primary health care and encourage the students of the school to enter a field of primary health care as a career choice.

Furthermore, foreign students are often accepted over American and legal alien students. As a result, America is exporting one of our greatest national resources - education - and taking away opportunities from qualified minority students. Under H.R. 3220, a grant or contract to a health professions school can be awarded only if the school agrees that, in considering applications for admission to the programs of health professions education operated by the school, the school will admit an individual who is not a citizen or permanent resident alien of the United States only if no qualified applicant who is such a citizen or alien is seeking admission.

The final vote on health care reform legislation will usher a new era of health care for all Americans. It's time to prepare our physician workforce for the 21st century, improve access, and cut costs.

Second, of the 80 million Americans who suffer from chronic back pain each year, 4 out of 5 cases could have been prevented. Back problems are the most common work injury today, usually striking people between the ages of twenty and fifty. According to The Power of Pain by Shirley Kraus, 100 million Americans are either permanently disabled or are less productive due to back pain. And, those who work lose about 5 work days per year, a productivity loss of \$55 billion.

Evidence now suggests that a significant number of these "failed backs"

are cases of adhesive arachnoiditis resulting from a myelogram, a diagnostic procedure that precedes surgery. In a myelogram, a radiopaque dye is injected into the spinal subarachnoid space. After the x-ray, as much of the oil as possible is withdrawn. However, the amount left behind often causes irritation and leads to arachnoiditis, an inflammation of the subarachnoid.

Symptoms of arachnoiditis include chronic nerve pain and a burning sensation which may attack the back, groin, leg, knee or foot and can result in loss of movement to almost total disability. Other symptoms include bladder, bowel, thyroid, and sexual dysfunction.

Harry Feffer, professor of orthopedic surgery at George Washington University states that patients who have had two or more myelograms stand a 50 percent chance of developing arachnoiditis. Furthermore, animal studies confirm the devastating effect of Pantopaque, an oil-based contrast medium, on the myelin sheath and nerve cells.

For several years, Members of Congress have repeatedly asked the Food and Drug Administration (FDA) to recall the use of Pantopaque. In 1987, Alcon, a subsidiary of Eastman Kodak, voluntarily stopped producing the drug due to public pressure. Pantopaque has a 5-year shelf date. The last batch of the drug was due to expire April 1, 1992. However, use of Pantopaque has continued, with reported usage as recent as September 1993. This evidence leads me to believe that Kodak is once again manufacturing Pantopaque. One final point I would like members of the Committee to know is that Pantopaque is still commonly used in veterans and military hospitals across the nation.

The bottom line is, the FDA clearly has not reviewed the safety of Pantopaque as well as water-based dyes, in spite of medical evidence. My bill, H.R. 2079 would recall the use of Pantopaque, Amipaque, Omipaque, and Isovue



in the myelogram procedure. My bill does not ban myelograms altogether, nor does it ban the use of these dyes outside of the myelogram procedure.

I understand my bill, as written, is stringent. I would be willing to make compromises based upon the findings of the Committee. Therefore, I would support a hearing on this bill which would include the participation of medical experts, the FDA, and sufferers of this disabling condition. I would then ask for the advice of the Committee on any further proceedings on H.R. 2079, as determined from the outcome of the hearing.

Additionally, H.R. 2079 provides for a thorough government study that would determine the number of Americans suffering from myelogram-related arachnoiditis and would explore medical findings showing this cause-and-effect relationship.

As I have previously mentioned, every year, chronic back pain is responsible for billions of dollars in lost revenues and millions of dollars added to the nation's health care bill. Unfortunately, people who develop arachnoiditis eventually become totally disabled and cannot work at all. They become permanent fixtures on the rolls of Social Security, disability, welfare, Medicaid, and Medicare.

As we undertake the reform of health care in America, it's time to protect unsuspecting Americans from this debilitating and preventable condition. I ask for your prompt consideration of my bill, H.R. 2079.

Third, studies show 20 percent or more of total medical costs go to maintain our current record-keeping system. The average hospital shuffles 5 million pieces of paper a year. A health card is inevitable.

No federal laws protect the privacy of medical records except those related to treatment for drug and alcohol abuse and psychiatric care and few states have

medical privacy laws. A health card could be used for numerous non-medical purposes. For example, a prospective employer could discover that your family has a history of heart disease and decide not to hire you. And as history has shown, during times of perceived crises, the government can and often does trample on individual liberty.

I have an amendment to the Clinton health care reform legislation that will protect consumers and cut government waste. My amendment proposes to combine the health card and Social Security card into a dual purpose card. All persons with access to medical or Social Security information should have a feature in their system that would block personal identifiers as well as block the use of Social Security or medical benefits should an individual qualify for one of the benefits and not the other. Furthermore, based on the principle that people have the right to control information about themselves, information collected should not be used for surveys or polls without an individual's consent. Likewise, information that needs to be shared between agencies, companies, hospitals, etc. should be stripped of all personal identification, such as name, address, etc., unless the information is vital or needed in case of emergency.

Ideally, we should be trusted as citizens to maintain our own medical database, much as we do our own credit card. Medical information could be backed up in an encrypted form at a private database company of choice. Doctors or hospitals could have access to this information with patient approval, or in case of an emergency.

My amendment also provides for an analysis of database companies currently able to provide this service or convert easily and what the conversion time factor would be. Under the study, an estimated cost to individuals should they want their records maintained as well as the cost of a government program that would subsidize or cover these costs for individuals who cannot afford to maintain their records but wish to do so. An analysis of projected participation and the cost to the government is also included.

Once again, I thank you, Mr. Chairman, and members of the Committee for the opportunity to testify. I ask for your consideration of the legislative initiatives I have presented here today. I would be more than happy to address any concerns or questions that you or members of the Committee may have.

Mr. PALLONE. Congresswoman DeLauro.

**STATEMENT OF HON. ROSA L. DeLAURO, A REPRESENTATIVE  
IN CONGRESS FROM THE STATE OF CONNECTICUT**

Ms. DeLAURO. Thank you. Thank you for the opportunity to be here today. I agree with the President that we need to pass in the Congress this year meaningful health care reform legislation, and that, in fact, that there should be the general principles, some which he has laid out, including guaranteed universal health care coverage, a comprehensive benefit package that includes preventive services that specifically addresses the needs of women and children, the chronically ill and disabled, that we have to assure quality care, and we have to reduce the waste and fraud in the system which amounts to about some \$80 billion a year.

I also have three specific areas that I wanted to mentioned, and I will be brief. One major concern that I have is that health care reform should address the issue of mental health care. It is an important issue, one that has been overlooked in health insurance for too long, in my view.

The President's plan would improve mental health care coverage, but it doesn't go far enough. On the other hand, his plan is better than most that are out there in terms of a beginning effort at mental health coverage. I am fully aware that the expansion of the coverage services has some budgetary implications. I also believe that we can be penny-wise and pound foolish in continuing to give mental health treatment second class status.

If you determine, if the committee determines that it is impossible to provide full coverage for all mental health services right away, I would encourage the subcommittee to consider taking one small additional step beyond the President's plan by providing full coverage for neurobiological disorders in the initial benefits package.

Insurance plans have discriminated against these disorders, which include Tourettes syndrome, autism, and obsessive compulsive disorder, because they have been classified as mental health disorders. The recent advances in science document that many of the severe mental illnesses are actually physical illnesses; in fact, neurobiological disorders.

I have introduced legislation, the Equitable Health Care for Neurobiological Disorders Act, which would ensure that health insurance plans would have to provide equitable coverage for neurobiological disorders on a par with the manner in which they cover other physical diseases.

Another issue about which I am concerned is graduate medical education. I represent a congressional district which is fortunate to have one of the finest academic health centers in the country, and a first rate health care professional community. However, I also represent an area which the Department of Health and Human Services says is a primary health care shortage area.

We need to make sure that whatever approach to graduate medical education we take in health care reform, that we wind up with the adequate number of primary care and specialist physicians in our underserved urban and rural areas, and that everyone has access to them.

I believe that we have to carefully consider what incentives we use to attract medical students into primary care practice, how we determine the number of specialists that we are going to need for the future, and how residency slots will be distributed and funded.

The Federation of Pediatric Organizations representing the community of practicing and academic pediatricians has developed a graduate medical education allocation and funding proposal, which you may wish to consider in the subcommittee's deliberations. The proposal calls for a creation of a National Health Care Work Force Commission, akin to the base closure type commission, that would determine the appropriate national number of allocation and allocation of residency slots.

Funding derived from all health care payers would be allocated directly to the programs, regional or local, or given to medical students as proposed in the commonwealth fund Task Force on Academic Health Centers. I submit the proposal from the Federation of Pediatric Organizations for your review as your deliberations go on.

The final matter I would like to touch on has to do with an issue that is really of great concern to senior citizens in my State. It is a glitch in the Medicare reimbursement for paramedic services provided on voluntary ambulance company ambulances.

When Connecticut seniors call for an ambulance, they often are billed hundreds of dollars for paramedic services that Medicare will not cover. Medicare will cover paramedic services when a commercial ambulance answers the call for help, but not when a volunteer ambulance takes a senior to the hospital.

A community-sponsored ambulance is often qualified to provide only the basic life support services, because they don't have highly trained paramedics that can perform the advanced life support services. So because the paramedic services are performed aboard the basic life support ambulance, neither the volunteer ambulance services nor the paramedic can bill Medicare for reimbursement. Unless the technicality in the Medicare law is changed, voluntary ambulance services may soon disappear and, quite frankly, for the small community, the small places that are in my district, we are really going to see lives endangered.

Again, I have introduced legislation that would allow for these intercept paramedics that provide the emergency life support aboard these nonprofit ambulances to apply directly to Medicare for reimbursement. They would be covered at the same rate under Part B of the Medicare Program that they would be as part of the commercial ambulance services. So I would ask you to take a look at that in your deliberations, and if you will give serious consideration to rectifying this in terms of health care reform legislation.

I thank you for the opportunity to be here today. I guess I am the last witness, so I guess we can go home or go to vote, and I really do appreciate the long hours that you have spent today at all of this. Thank you very, very much.

[The prepared statement of Ms. DeLauro follows:]



## Statement of the Hon. Rosa L. DeLauro

Mr. Chairman. I want to thank you, Rep. Bliley, and all of the Members of the Subcommittee for allowing me the opportunity to testify before you today about health care reform. I know how hard you have all worked over the past several months and how difficult your job over the next several weeks will be, so I deeply appreciate your arranging this afternoon's hearing so that my colleagues and I can share our concerns with you.

Mr. Chairman, The President's State of the Union address crystallized the debate between those who believe we have a major health care problem and those who believe things are just fine. The President clearly and forcefully restated the case for reform and I firmly agree with his call for the Congress to pass meaningful health care reform legislation this year. Those who don't believe there's a health care crisis have not been talking to the people I see in my district every week. I do not want to hold any more office hours in my home town where hour after hour people tell me heart-breaking stories about their need for health insurance. We must make sure that no American, ever, will lose his or her health care because they change jobs or get sick. We must also make sure that if you are fortunate enough to survive a serious illness that, subsequently, you cannot be denied health care coverage. If we fail to boldly address these shortcomings in our current system, we will have squandered a tremendous opportunity.

I believe the final product should reflect the President's health care bill's principles, including: guaranteed universal health care coverage; a comprehensive benefits package that includes preventive services and addresses the special needs of women, children, the chronically ill and disabled; assuring high quality care; and reducing waste, fraud and abuse to keep costs down. We must devote the resources necessary to aggressively go after those who commit fraud now, roughly \$80 billion dollars worth, and build in safeguards against the potential for new ways our system may be abused.

In addition to these general principles, there are a few specific concerns I wish to discuss with you today. One major concern I have is that health care reform should address mental health care, an important and too long overlooked element of health insurance. The President's plan would improve mental health care coverage, but it does not go far enough. On the other hand, his plan is better than most of the competing proposals. While I am fully aware that any expansion of covered services has budgetary implications, I also believe we can be penny wise and pound foolish in continuing to give mental health treatment second class status. In fact, according to the National Institutes of Mental Health, equitable insurance coverage for severe mental disorders would yield \$2.2 billion annually in net health care savings through decreased use of general medical services and decreased social costs.

If you determine it is not possible to provide full coverage for all mental health services right away, I would encourage your Subcommittee to consider taking one small additional step beyond the President's plan by providing full coverage for neurobiological disorders in the initial benefits package. In the same manner in which they have limited coverage for all mental health problems, insurance plans have discriminated against these disorders, which include Tourette's disorder, autism, and obsessive-compulsive disorder, because they have been classified as "mental health" disorders. However, recent advances in science document that many severe "mental" illnesses are actually physical illnesses -- neurobiological disorders -- that are characterized by significant neuroanatomical and neurochemical abnormalities. Legislation I introduced, the Equitable Health Care for Neurobiological Disorders Act, would ensure that health insurance plans would have to provide equitable coverage for neurobiological disorders on a par with the manner in which they cover other "physical" diseases.

Another issue about which I am greatly concerned is graduate medical education. I represent a Congressional District which is fortunate to have one of the finest academic health centers in the country and a first-rate health care professional community. However, I also represent an area which the Department of Health and Human Services says is a primary health care shortage area. We must make sure that whatever approach to graduate medical education we take in health care reform, we wind up with adequate

numbers of primary care and specialist physicians in our underserved urban and rural areas, and that everyone has proper access to them.

The President's proposal calls for a dramatic increase in the number of primary care physicians we train versus specialists. While there seems to be a consensus that we need to move in that direction, there is a lot of concern about how we achieve the proper physician mix. I believe we must carefully consider what incentives we use to attract medical students into primary care practice, how we determine the number of specialists we will need in the future, and how residency slots will be distributed and funded. The Federation of Pediatric Organizations, representing the community of practicing and academic pediatricians, has developed a graduate medical education allocation and funding proposal you may wish to consider in your Subcommittee's deliberations on this matter. In short, this proposal calls for the creation of a National Health Care Workforce Commission that would determine the appropriate national number and allocation of residency slots. Funding, derived from all health payers, would be allocated directly to programs, regional or local consortia, or given to medical students as proposed in a Commonwealth Fund task force report on academic health centers. With your permission, I would like to submit for your review and for the record, copies of this proposal and the Commonwealth Fund report.



The final matter I'd like to touch upon has to do with an issue that is of great concern to senior citizens in my state -- a glitch in Medicare reimbursement for paramedics' services provided on voluntary ambulance company ambulances.

When Connecticut seniors call for an ambulance, they often end up stuck with an enormous medical bill they cannot afford to pay. They are billed hundreds of dollars for paramedic services that Medicare will not cover. Medicare will cover paramedic services when a commercial ambulance answers the call for help, but not when a volunteer ambulance takes a senior to the hospital. The result is seniors who are scared to call 911, and towns that cannot afford to continue providing volunteer ambulance services to their communities.

Community-sponsored ambulances often qualify to provide only Basic Life Support (BLS) services, because they don't have the highly-trained paramedics necessary to perform Advanced Life Support (ALS). When necessary, community BLS ambulances borrow paramedics from commercial ALS ambulances. Because the paramedic services are performed aboard a BLS ambulance, neither the volunteer ambulance services nor the paramedic can bill Medicare for reimbursement. Unless this technicality in Medicare law is changed, volunteer ambulance services may soon disappear, and lives could be endangered. If communities give up their volunteer ambulances, they will be forced to rely on commercial ambulance services that often must travel longer distances to

pick up patients, wasting precious minutes that can mean the difference between a senior's life and death.

I have introduced legislation that would allow "intercept" paramedics providing emergency life-support aboard non-profit ambulances, to apply directly for Medicare reimbursement. These intercept paramedics would be covered at the same rate, under part B of the Medicare program, that they would as a part of a commercial ambulance service. Intercept service will only be billable to Medicare if transportation services are provided by a town-sponsored non-commercial ambulance corp. The paramedic providing these services must meet the same qualifications Medicare currently requires for paramedics as part of full ALS services. I would ask that you give serious consideration to rectifying this situation as you deliberate health care reform legislation.

Again, I want to thank you all very much for providing me with this opportunity to testify today. You have a tremendous and important task ahead of you, and I look forward to working with you in any way you deem appropriate.

Mr. PALLONE. Thank you, Rosa, and thank all of you.

Let me just say, I noticed a number of you mentioned primary care and the fact that the President's proposal relies so much on the existence of primary care physicians, providers, and how that is linked to the whole issue of medical education. And it is a real problem. I mean we—

I think all of us realize, and I certainly do, just talking to some of the physicians and hospital administrators that have come to see me, that it is nice to talk about how we are going to emphasize primary care and create incentives for it, but right now when you talk about medical education, most doctors who are in training, you know, are not primary care, and they are not really interested in it. Or at least a lot aren't. So I don't know.

It is a problem figuring out how we are going to deal with that and how we are going to get some more people into primary care, not only physicians but other health care professionals as well. So, I don't know, Congressman Hall, did you have anything you wanted to—

Mr. HALL. Well, nothing, except I think there have been very good presentations and I think with the presentation that sometimes we need the facts on the cost and what your proposal saves and what it does for us. That is going to be very important to the First Lady because she is looking for money right, left, and sideways now to fund the health plan that she is proposing, and I think it would be helpful to her, too.

And I would say to Mr. Traficant, on your card bill, would that have a picture on it also?

Mr. TRAFICANT. It doesn't call for it, it just creates the card, and that would be up to the Congress. And it certainly would probably make sense to have it. With all the magnetic technology they have now, that could also be incorporated into it.

Mr. HALL. Looks like it would help them, not a card that someone could use against them, but could use in their behalf to even cash checks and things like that. It would be very helpful. And on your myelographic—are you outlawing any type of myelographic study?

Mr. TRAFICANT. No, no, we are not, but we are banning those that leave a residue that produces those problems. And the medical community is saying it does cost more to have the magnetic resonance imaging, but they are much safer and they are beginning to bring the cost down on these MRI's and they are suggesting that be a far greater technology and the use of these dyes is leaving people chronically dysfunctional for the remainder of their life and being wards of social security and the government. That is one of the findings on that case dealing with myelograms.

Mr. HALL. Of course, everyone hopes that they can—no one wants to have a myelographic study done. I don't know if you have ever seen one.

Mr. TRAFICANT. No.

Mr. HALL. I used to practice personal injury law, and I always had my doctor testify they were total and permanent, and their insurance company doctor would testify, if they had a leg off it would grow back, you know. And they all wanted a myelographic study. And if you spring that—if you bring that hook in there that they

use for myelographic study, it always had the impression on the jury that it would have had on me. It was a frightful looking thing and people have died undergoing myelographic studies.

If there is a way around them, I think you are doing a great service to probe this and to give them an alternative. MRI certainly should be an alternative. And just as the television sets which were this big around with sets that wide, technology is going to overtake us and help us in the fields that you have laid out there. Of course, Mr. Coleman knows I am for his bill.

I say, Ron, that your type legislation is the very type legislation that your folks sent you here to do and I know you well enough to know it is right down your line, that you really believe it, you really feel it. I live inland from the border, from the 2,000 mile Rio Grande border, but we have many Mexicans that step across that river that come up into our area looking for work and looking for help. And they work and they give you a hard day's work, and because they are family-oriented, because they care about their families, they send 90 percent of that money back to take care of their own. They are pretty good people. I think your bill is certainly on track.

Mr. COLEMAN. Well, appreciate your cosponsorship, Mr. Hall. Let me just say to everyone here, that—two things. First of all, that that is the point also about border health issues. When we talk about them, everybody needs to know, the problem isn't staying on the border. We have a program whereby migrant workers work all over the United States. They are in Mr. Traficant's district and Ms. DeLauro's district, and yours, Mr. Chairman, mine, everywhere. And if, in fact, we don't believe that we have a common problem, then we don't understand the problem. That is my real view.

In fact, when I introduced the legislation, Ralph, Mr. Hall, one of the things I did was, of course, I also shared it with some of our counterparts in Mexico, to see what their review of a U.S.-Mexico Commission would be. As you know, we already have a International Boundary and Water Commission where we meet on a regular basis to deal with, again, problems on the river and the way it flows, the taking of water from the Rio Grande. We do all of those things on a regular basis. It is nothing new.

In fact, the response was communicated to me shortly after the introduction of the legislation by the ambassador to the United States from Mexico, who called me to his office and told me that the response from Mexico is very positive. Because I had also in my letter suggested, when my legislation suggested and I wanted to raise the issue because you did, Ralph, about how we pay for things, a part of this commission idea was, of course, that we can share some of these costs together with Mexico and the United States for the care of patients in each other's country.

As you may know, many of my constituents, and I am sure some of yours that you may not even know about, shop for drugs, for example, prescription drugs, in Mexico. They are cheaper. Get the same drug, it may be under a different name, but you will get the same drug and they are cheaper. We are utilizing Mexico's facilities for our own health care.

A lot of people may not believe that or may not know that too much, but we are doing a lot of it, not just in that field, but in oth-



ers. I would suggest to you that we have some common problems, some common things that we need to do. And you and I know, Ralph, that many—we found that if we can get women to come for the kinds of radiological tests that are needed for breast and cervical cancer and other things, we get many of the women, they bring their children and we are able to immunize them simultaneously. We are doing a lot of things. And this is from an old house trailer right there in my county. I fought like crazy with HHS just to give us some help to get the house trailer. We didn't succeed, so we did it locally.

Those are the kinds of things, that is what we have got to understand is in an overall, and believe me, you know, I am a strong supporter of this idea of universal health care coverage. There is no question from my district where we need to be on this kind of an issue. I have got so many people that just do not have health care and don't have the coverage and many literally have a hard time even accessing it.

Everybody says, well, everybody gets it, some in the most expensive way. Let me just tell you, even because of the wide expanses out in west Texas, many people are not getting the health care they ought to get and they will ignore it. As you know, if you ignore something that is a problem, you will pay for it again later. We will, at a greater, much higher cost.

So I compliment the administration first and foremost for staying with their guns and drawing the line in the sand where they have done it. We need to have universal health care coverage, at least from the perspective of my district. Thank you very much, Mr. Chairman.

Mr. PALLONE. OK.

Mr. HALL. Mr. Chairman, could I ask one other question of Ms. DeLauro?

Does your proposal address both psychiatry and the psychologist?

Ms. DELAURO. It addresses this whole issue of neurobiological disorders, and I wanted to make the point to you because you asked what is a very, very relevant question on the cost. And all of this is related to cost.

The whole purpose, in my view of health care reform, is to try to do something about cost. And the National Institutes of Health have done the study that says equitable insurance coverage for these severe mental disorders, and these Tourettes, autism, obsessive compulsive disorder, schizophrenia, it would yield a \$2.2 billion annually net health care savings.

It costs us now somewhere around \$8.7 billion to care for people who have these disorders. And this would—the coverage, insurance coverage, would be about \$6.5 billion. So we would save money in effect.

Mr. HALL. You have got a savings there? I will accentuate, it is important.

Ms. DELAURO. Now, clearly, there is a debate within the medical community about what are neurological disorders, and other kinds of mental illnesses. Because these are regarded as physical illnesses, there is a higher rate of success in treating some of these disorders than there is with heart trouble or cancer. We have done so much scientifically in these areas except that these folks are

then dealing with the stigma of a mental disorder and get no relief on the health insurance side. It really is unfair.

Mr. HALL. I thank you for that and I thank you all. You make your next presentation. Mr. Regula, you always do such a good job, I can't think of anything to ask you.

Mr. PALLONE. Thank you to all the panelists. This concludes the hearing.

[Whereupon, at 4:17 p.m., the subcommittee was adjourned, to reconvene at the call of the Chair.]

[The following statements and letters were submitted:]

STATEMENT OF THE HONORABLE BARBARA VUCANOVICH  
BEFORE THE SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT  
FEBRUARY 2, 1994

MR. CHAIRMAN, I APPRECIATE THIS OPPORTUNITY TO COME BEFORE THIS SUBCOMMITTEE ON THE ISSUE OF HEALTH CARE REFORM. THEY SAY IF YOU EAT AN APPLE A DAY YOU CAN KEEP THE DOCTOR AWAY. BUT HOW CAN WE KEEP CONGRESS AWAY FROM DESTROYING OUR HEALTH CARE SYSTEM WHICH DOES HAVE ITS PROBLEMS, BUT HAS BEEN ABLE TO PROVIDE MILLIONS OF AMERICANS WITH THE HIGHEST QUALITY HEALTH CARE IN THE WORLD? THE ANSWER IS SIMPLE: LISTEN TO THOSE AMERICANS WHO PUT US IN OFFICE. I HAVE LISTENED TO THE PEOPLE IN NEVADA WHO HAVE WRITTEN TO ME OR ATTENDED ONE OF MY MANY HEALTH CARE FORUMS LAST YEAR, AND THEY DO NOT WANT OUR GOVERNMENT INVOLVED IN THEIR HEALTH CARE SYSTEM.

YET THE CLINTON ADMINISTRATION IS WILLING TO TAKE OUR CITIZENS' FREEDOM AWAY BY DETERMINING WHAT TYPE OF HEALTH CARE IS NEEDED AND WHO WILL PAY FOR IT. OUR WHOLE NATION WILL BE PAYING FOR IT - I SAY THIS BOTH LITERALLY AND FIGURATIVELY.

SMALL BUSINESSES IN NEVADA AND THROUGHOUT THE NATION FEAR THE CLINTON PLAN. AT A TIME WHEN WE SHOULD ENCOURAGE ENTREPRENEURS, THE CLINTON PROPOSAL DISCOURAGES THEM BY REQUIRING THAT BUSINESS FUND OUR HEALTH CARE SYSTEM. WITH OR WITHOUT A SUBSIDY, SMALL BUSINESSES WILL BE FORCED TO PAY AN EMPLOYER BASED MANDATE -- IN OTHER WORDS, A PAYROLL TAX. WHEN ASKED ABOUT HOW THEY WOULD BE AFFECTED BY A 3.5% INCREASE IN PAYROLL COST IN A AUTUMN GALLUP POLL, ONE THIRD OF BUSINESS OWNERS RESPONDED THAT THEY WOULD LET EMPLOYEES GO AND NEARLY ONE HALF SAID THEY WOULD BE FORCED TO RAISE PRICES ON THEIR PRODUCTS OR SERVICES. HOW CAN WE EVEN SPEAK ABOUT HEALTH SECURITY, WHEN IT WILL COME AT THE EXPENSE OF JOB SECURITY?

ALREADY, NEVADANS ARE FEELING THE EFFECTS OF THE CLINTON PROPOSAL. I HAVE HEARD THAT ONE BUSINESSMAN IN RENO, NEVADA HAS EVEN DECIDED TO HOLD BACK ON PLANS FOR EXPANSION, FEARFUL THAT A PROMISING BUSINESS WILL GO DOWN THE DRAIN IF HE IS REQUIRED TO MEET THESE NEW FINANCIAL REQUIREMENTS.

BUSINESSES ARE NOT THE ONLY ONES WHO ARE ALREADY FEELING THE EFFECTS OF CHANGES PROPOSED UNDER THE CLINTON ADMINISTRATION. WOMEN, TOO, ARE SEEING CHANGES IN THEIR HEALTH CARE. THIS YEAR, THE NATIONAL CANCER INSTITUTE CHANGED ITS RECOMMENDATIONS ON THE NEED FOR MAMMOGRAPHY FOR WOMEN. AT ALMOST THE SAME TIME, THE CLINTON ADMINISTRATION OFFERED ITS HEALTH CARE PROPOSAL, LIMITING ACCESS TO MAMMOGRAPHY SERVICES TO ONCE EVERY TWO YEARS. ALREADY, WE HAVE SEEN SOME INSURANCE COMPANIES PULLING BACK MAMMOGRAPHY COVERAGE. SUFFERING THE MOST FROM THESE CHANGES ARE WOMEN OF POORER MEANS, WHO ALREADY FIND DIFFICULTY IN ACCESSING QUALITY HEALTH CARE, LET ALONE PREVENTATIVE CARE.

THE CLINTON ADMINISTRATION CLAIMS TO IMPROVE THE QUALITY OF CARE

FOR WOMEN, YET MAMMOGRAPHY SERVICES ARE LIMITED TO ONCE EVERY TWO YEARS FOR WOMEN 50 YEARS OF AGE OR OLDER. THIS IS QUITE BAFFLING TO ME SINCE THE NATIONAL CANCER INSTITUTE AND THE AMERICAN CANCER SOCIETY RECOMMEND AN ANNUAL MAMMOGRAM FOR WOMEN OF THAT AGE GROUP. IF ANYTHING, THESE SERVICES NEED TO BE INCREASED. THAT IS WHY I HAVE INTRODUCED LEGISLATION TO INCREASE MEDICARE COVERAGE OF MAMMOGRAPHY TO ONCE A YEAR FOR WOMEN AGED 65 AND OLDER. I THINK THIS IS SOMETHING THAT CONGRESS CAN AGREE UPON SINCE 160 COSPONSORS, BOTH DEMOCRATS AND REPUBLICANS ALIKE, ARE ON THE BILL. IF WE ARE TO REFORM HEALTH CARE TO IMPROVE THE HEALTH FOR WOMEN AND MEN ALIKE, AND IMPROVE THE ACCESSIBILITY OF HEALTH CARE TO INDIVIDUALS, THESE SERVICES SHOULD BE PROVIDED AT A FREQUENCY WHICH WILL ACTUALLY HELP THE INDIVIDUAL. TWO YEARS IS A LONG TIME IN WHICH A TUMOR CAN GROW AND KILL.

LASTLY, BUT OF NO LESS SIGNIFICANCE IS HOW THE CLINTON HEALTH CARE PLAN WILL AFFECT RURAL COMMUNITIES. I REPRESENT A STATE WHOSE RURAL POPULATION MAKES UP 17% OF THE STATE AND 87% OF THE LAND MASS AREA. THE LARGE PERCENTAGE OF MEDICARE AND MEDICAID POPULATIONS WHO RESIDE IN RURAL COMMUNITIES WILL BE SEVERELY IMPACTED BY CUTS TO THE MEDICAID PROGRAM IN A DISPROPORTIONATE WAY. I AM CONCERNED, ALSO ABOUT HOW THE FORMATION OF REGIONAL HEALTH ALLIANCES WILL AFFECT THE RURAL POPULATIONS. WHILE SOME HAVE PROPOSED THE DESIGNATION OF HEALTH PROFESSIONS SHORTAGE AREAS, THIS HAS NOT ADDRESSED THE FACT THAT ONE PHYSICIAN WILL LIKELY BE THE SOLE PROVIDER FOR A VERY LARGE AREA. WITHOUT AN INCREASE IN PROVIDERS, HEALTH CARE WILL NOT IMPROVE FOR RURAL COMMUNITIES.

RURAL AREAS MUST BE CONSIDERED ON THEIR OWN MERITS. URBAN HEALTH POLICIES CANNOT BE RETROFITTED TO INCLUDE RURAL POPULATIONS. IT JUST WON'T WORK. RURAL POPULATIONS HAVE SPECIAL NEEDS AND DESERVE THE SAME QUALITY AND ACCESS TO CARE AS URBAN POPULATIONS. THE ADMINISTRATION'S ATTEMPT TO SECURE HEALTH CARE FOR THESE PEOPLE IS ADMIRABLE BUT FALLS SHORT OF WHAT IS NEEDED. I ENCOURAGE THIS SUBCOMMITTEE TO WORK WITH THE HOUSE RURAL HEALTH CARE COALITION AND TO VISIT RURAL STATES, LIKE NEVADA, TO DETERMINE HOW CONGRESS CAN BEST MEET THE SPECIAL NEEDS OF OUR RURAL CITIZENS.

MR. CHAIRMAN, THERE ARE SO MANY CONCERNS I HAVE ABOUT THE CLINTON PLAN. I AM PLEASED THAT THE SUBCOMMITTEE IS HOLDING THESE HEARINGS TO LISTEN TO MY CONCERNS, AND THOSE OF MY COLLEAGUES, PERTAINING TO THE CLINTON PLAN AND HOPE THAT CONGRESS WILL PROCEED CAUTIOUSLY. HASTE MAKES WASTE -- LET'S NOT WASTE THE QUALITY HEALTH CARE OUR WHOLE NATION HAS COME TO ENJOY AND TO EXPECT.

THANK YOU MR. CHAIRMAN.





CENTER FOR HEALTH POLICY RESEARCH

February 2, 1994

The Honorable Henry A. Waxman  
Chairman, Subcommittee on Health and the Environment  
Committee on Energy and Commerce  
U.S. House of Representatives  
2408 Rayburn House Office Building  
Washington, D.C. 20515

Dear Chairman Waxman:

We wish to submit for inclusion in the Subcommittee's national health reform hearing record today preliminary information from a study we are preparing for the Henry J. Kaiser Commission on the Future of Medicaid and The Commonwealth Fund. This study will assess the degree to which various national health reform proposals now under Congressional consideration assure low and moderate income working families financial assistance in paying for private health insurance.

The three measures we have analyzed are H.R. 3600 (the Health Security Act); H.R. 3222 (The Managed Competition Act); and H.R. 3704 (The Health Equity and Access Reform Today Act). We have selected these three measures because of their similarities and differences. On one hand, all three bills incorporate a premium-based approach to health coverage and seek to achieve universal health coverage by expanding access to affordable private, group purchased health insurance. On the other hand, the bills take highly different approaches to financing coverage for working Americans. These differences yield dramatically different results for working families. Indeed, our results suggest that neither H.R. 3222 nor H.R. 3704 may significantly reduce the number of uninsured workers and their families. This is because, even after full implementation of either bill, coverage still would be unaffordable for millions of working families with modest incomes.

## 1. Relative levels of premium assistance

Table 1 shows the level of premium assistance provided to low and moderate income working families under the three measures. We have calculated the premium assistance impact of each bill, using a family of 3 headed by a full-time worker, 1993 federal poverty level data, and a group health plan premium whose 1993 dollar price would be considered average by HCFA.<sup>1</sup>

H.R. 3600: In the case of H.R. 3600, employers bear 80 percent of the premium cost for full-time workers and their families, leaving low and moderate income workers with out-of-pocket premium costs that amount to no more than 3.9 percent of their taxable income.

In the case of H.R. 3704 and H.R. 3222, however, the family's potential premium burden is far greater. This is because the only assured premium subsidy comes from the public subsidy system specified under each bill and because neither subsidy system appears to be adequate to assure affordability.

H.R. 3704: Under H.R. 3704, individuals receive vouchers to buy insurance through purchasing groups. Voucher assistance begins for individuals with incomes at or below 90 percent of the federal poverty level and expands annually up to 240 percent of the poverty line by the year 2005. In that year, a family of 3 with taxable income amounting to 180 percent of the federal poverty level (\$21,400 in 1993 dollars) would have to pay more than \$2100 in premium costs alone for health coverage. This amounts to 10 percent of the family's annual taxable income. A family with taxable income amounting to 250 percent of the federal poverty level would have health insurance premium costs of over \$3700. This premium burden amounts to 12.5 percent of the family's annual taxable income. This finding is significant, since economists have suggested that a family's maximum out-of-pocket liability for all health costs -- premiums, deductibles, coinsurance and uncovered health expenses -- should not exceed 10 percent of wages.

H.R. 3222: H.R. 3222 shows even more dramatic results. Under the bill, subsidies are available to low and moderate income families with taxable incomes up to only 200 percent of the poverty level.<sup>2</sup> Moreover, unlike H.R. 3600, the premium financing system in H.R. 3222 does not assume a premium payment structure for low and moderate income workers equal to the price of at least the average cost plan. Instead, health plans would be required to absorb a significant portion of the premium cost through a sizable discounting

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<sup>1</sup>In the case of H.R. 3222, two additional assumptions unique to their bill were necessary in order to conduct the analysis. First, the national subsidy percentage was projected to be 90 percent. Secondly, the reference premium rate was presumed to be equal to the average premium amount. In both cases, we attempted to make the most favorable assumptions in order to display the maximum potential impact of the measure.

<sup>2</sup>The measure would also revise the federal poverty level to make it state-specific. For the sake of simplicity here, we have used the current federal poverty level structure.

system. In our opinion this discounting arrangement would seriously limit the willingness of health plans to market to low and moderate income workers.

The financial impact of H.R. 3222 on workers can be seen on Table 1. Under the measure, a family with taxable income no greater than twice the federal poverty level (\$23,780 for a family of 3 in 1993 dollars) would be guaranteed no discount or subsidy and would pay \$3,709 for health coverage. This premium burden amounts to 15.6 percent of the family's annual income. A family with taxable income as low as 150 percent of the federal poverty level would still be required to pay annual premiums amounting to more than 10 percent of annual taxable income.

## 2. The impact of declining premium assistance for workers moving out of poverty

Table 2 shows the "cliffs" that occur for low income working families as they move out of poverty and the already limited subsidies provided under H.R. 3600, H.R. 3704 and H.R. 3222 as they are phased out. These calculations are of particular importance, because they show the impact of insufficiently financed premium subsidies on the overall well-being of low and moderate income workers as they attempt to better their financial situation.

In the case of a worker whose earnings increased from 100 percent to 150 percent of poverty, under H.R. 3600 the worker's annual premium liability would increase by \$339, while her wages would grow by \$5,945. Thus the "price" of her salary increase amounts to only 5.7 percent of her additional earnings. Under H.R. 3704, however, the worker would lose more than 22 percent of her additional earnings to higher health insurance premiums. Under H.R. 3222, the "price" of moving out of poverty would be over 31 percent of her additional earnings. Put another way, under H.R. 3222, for each additional dollar our hypothetical worker earns, more than 30 cents are lost immediately to higher health insurance premiums. These cliffs, when combined with the relatively high cost of coverage for near-poor and moderate income workers, act as a powerful work disincentive. More importantly, perhaps, they would deprive families with modest incomes of the funds they need to meet other basic necessities of life.<sup>3</sup>

In the end, the most important question Congress must confront is which plan does the most for those families who constitute the bulk of uninsured Americans today -- full-time workers earning low or modest incomes and their families. These tables suggest that unless direct public subsidies are financed at far higher levels than those contemplated under either H.R. 3704 or H.R. 3222, legislation to aid the uninsured may provide little meaningful help to the working uninsured. Even for a family earning the median income (approximately \$30,000) the cost of health insurance under either bill would exceed 10 percent of its annual income and would be virtually unaffordable in the absence of an assured subsidy.

We thank you for including this information in the hearing record.

Sincerely,

*Sara Rosenbaum*

Sara Rosenbaum, J.D.  
Senior Research Staff Scientist

*Julie Darnell*

Julie Darnell, M.H.S.A.  
Research Associate

<sup>3</sup> We should also note that the cliff would be even greater were we to factor in the added loss of the earned income credit, which would take place as her wages increased.

Table 1

PREMIUM ASSISTANCE FOR LOW AND MODERATE INCOME WORKING FAMILIES UNDER SELECTED HEALTH REFORM PROPOSALS																
Family Chooses Average-Priced <sup>1</sup> Health Insurance Plan (\$3,709)																
		Clinton/Gephardt/Mitchell HR 3600/ S 1757						Thomas/Chafee HR 3704/ S 1770				Cooper/Breaux HR 3222/S 1579				
Pov. Lev.	Family <sup>2</sup> Income <sup>3</sup>	Subsidy	Firm Pays	Plan Pays	Family Pays	% of Family Income	Subsidy	Firm Pays	Plan Pays	Family Pays	% of Family Income	Subsidy	Firm Pay <sup>6</sup>	Plan Pays	Family Pays	% of Family Income
100	11,890	385	2967	0	357	3.0	3709	0	0	0	0	3338	0	371	0	0
130	15,457	278	2967	0	464	3.0	2914	0	0	795	5.1	2337	0	260	1133	7.2
150	17,835	46	2967	0	696	3.9	2384	0	0	1325	7.4	1669	0	185	1855	10.4
180	21,402	0	2967	0	742	3.5	1590	0	0	2119	9.9	668	0	74	2967	13.9
200	23,780	0	2967	0	742	3.1	1060	0	0	2649	11.1	0	0	0	3709	15.6
250	29,725 <sup>4</sup>	0	2967	0	742	2.5	0	0	0	3709	12.5	0	0	0	3709	12.5

<sup>1</sup> Based on HCFA's estimate of the 1994 average premium cost (\$3,894) of health plan for one adult family, deflated to 1993 dollars by assuming 5% growth in CPI

<sup>2</sup> Family of three; full-time working mother with two dependents; not receiving AFDC or SSI

<sup>3</sup> Poverty guidelines, 1993; adjusted gross income (taxable income)

<sup>4</sup> Median income for all households in 1991 was \$30,126; Statistical Abstract of the U.S., 1993

<sup>5</sup> Calculated assuming 90% national subsidy and base Federal premium of \$3,505

<sup>6</sup> Assumes no voluntary employer contribution toward cost of premium



Table 2

IMPACT OF SUBSIDIES UNDER SELECTED HEALTH REFORM PROPOSALS ON LOW AND MODERATE INCOME FAMILIES AS THEY INCREASE EARNINGS									
<i>Family Chooses Average-Priced<sup>1</sup> Health Insurance Plan (\$3,709)</i>									
		Clinton/Gephardt/Mitchell HR 3600/ S 1757		Thomas/Chafee HR 3704/ S 1770		Cooper/Breaux HR 3222/S 1579			
Increase in Poverty	Dollar Amount of Increase in Wages	Dollar Amount of Additional Increase in Premium Liability for Family	Percent of Wage Increase Devoted to Premium	Dollar Amount of Additional Increase in Premium Liability for Family	Percent of Wage Increase Devoted to Premium	Dollar Amount of Additional Increase in Premium Liability for Family	Percent of Wage Increase Devoted to Premium		
100 → 150	5,945	339	5.7	1325	22.3	1855	31.2		
130 → 180	5,945	278	4.7	1325	22.3	1855	31.2		
150 → 200	5,945	46	.7	1325	22.3	1855	31.2		
200 → 250	5,945	0	0	1060	17.8	0	0		

<sup>1</sup> Based on HCFA's estimate of the 1994 average premium cost (\$3,894) of a health insurance plan for one-adult family, deflated to 1993 dollars by assuming 5% growth in the CPI

## HEALTH CARE REFORM

### Long-Term Care and Quality Assurance

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THURSDAY, FEBRUARY 3, 1994

HOUSE OF REPRESENTATIVES,  
COMMITTEE ON ENERGY AND COMMERCE,  
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT,  
*Washington, DC.*

The subcommittee met, pursuant to notice, at 10:12 a.m., in room 2123, Rayburn House Office Building, Hon. Henry A. Waxman (chairman) presiding.

Mr. WAXMAN. The meeting of the subcommittee will come to order.

Today, we continue our review of President Clinton's Health Security Act with a focus on two important issues: long-term care and quality assurance. If you ask Americans the best way to live out their last days, most would say they would like to do it quietly at home. If you ask them the worst way to spend the rest of their lives, they would say years of bankruptcy and loneliness in a nursing home.

For those who share these worries and fears, America's elderly and disabled, these problems have become real health care catastrophes, for their family members as well, many of whom must now leave jobs and forego retirement savings to provide care for their loved ones. These catastrophes are very much part of the Nation's health care crisis.

For these millions of Americans, there is no true health reform without long-term care reform. There can be no comprehensive health care without home care and nursing home care. There can be no complete health financing plan without a plan to pay for disability and chronic diseases.

The Clinton health reform plan takes important steps in this direction. It makes access to home- and community-based services for people of all ages a top priority. It includes only modest improvements in nursing home services, but does begin to focus on the need for real health reform in this area, and as we discussed in a previous hearing, the President's program establishes real consumer protections for those who wish to finance their long-term care needs through the purchase of private insurance.

The President's bill also offers a new approach to quality assurance, a performance-based program based on monitoring health care outcomes, consumer surveys and public disclosure of health plan performance. The bill also calls for a stepped up research ef-

fort on quality assurance and an expanded program for the development of clinical practice guidelines.

All of us want to assure that the quality of care under health reform meets the highest standards, especially as more and more people choose to enroll in managed care plans. We certainly need to have explicit quality standards in place and the capacity to monitor health plans. Too often in the past the failure to hold providers and plans accountable for their performance has put patients at great risk. There is no substitute for vigorous oversight by States and the Federal Government as we make such sweeping changes in the health system.

Before calling on our first witnesses, I want to recognize members of the subcommittee for opening statements. I would like, first of all, to ask unanimous consent that all members have an opportunity to insert an opening statement in the record at this point, and I want to recognize Mr. Greenwood first.

Mr. GREENWOOD. Thank you, Mr. Chairman. I don't have an opening statement per se. I would simply like to welcome Orien Reid, who is a friend and neighbor from the Philadelphia region. She is a member of the national board for the Alzheimer's association. We are very much looking forward to her testimony which comes straight from the heart and from her personal experience. I would like to welcome you, Orien.

Mr. WAXMAN. Thank you, Mr. Greenwood.

Mr. Wyden.

Mr. WYDEN. Thank you, Mr. Chairman. I want to commend you and our staff. I think this is a very important hearing and you all have been leading this fight for a long time. With respect to long-term care, I think we know that one of the great tragedies in this country is that literally millions of older people scrimp and save all their lives and try to plan for their retirement and then they or their spouse is faced with long-term care costs and they are literally wiped out.

What is important about the Clinton long-term care initiative, the initiative proposed in his bill, is they are the beginning of a long-term care policy for our country. They are the first steps. They go to the heart of what a long-term care ought to be, which is to make sure that the older people and disabled people have the option for services in their home, and it seems to me in the fight to develop a long-term care policy for our country, the Clinton legislation is a good start, and I hope my colleagues will support it.

With respect to quality, Mr. Chairman, I want to thank you and your staff in particular for having worked with me for a number of months because I intend in the committee to offer an alternative approach to the Clinton legislation in the quality area.

It seems to me that quality and quality issues have gotten short shrift in the debate about health care in our country. The vast majority of attention has been paid to the question of cost. It seems to me that if you really want to hold down cost, you better take steps to enhance quality, because if the health system has to come back after their botched surgeries, for example, or misdiagnoses, costs are going to go up and people in this country will suffer. So I intend in committee to offer an alternative approach in the qual-



ity area that will bring a more activist approach to dealing with quality.

It seems to me that the Clinton bill, again, is a good start but it consists mostly of monitoring quality on paper, reviewing a great deal of paper and forms and the like. What I would like to do is take a more activist approach and when there is evidence of a provider who is not delivering good quality care, what we want is for officials in the health system to bring that to the attention of plans and providers, sit down with them, go over the problem, look at a remedial plan, and try to deal with it in a much more activist way.

Mr. Chairman, you and your staff have been very helpful in terms of working with us on this. I look forward to this important hearing.

Mr. WAXMAN. Thank you very much, Mr. Wyden.

I am now pleased to recognize the distinguished ranking republican member of the subcommittee, Mr. Bliley.

Mr. BLILEY. Thank you, Mr. Chairman.

The central focus of the administration's long-term care benefit is a new home- and community-based services capped entitlement. The programs' eligibility is based on an individual's level of cognitive and functional disability. This benefit would provide a broad array of services to disabled individuals of all ages. Overall, I applaud the administration's focus on providing services to disabled persons in a home- and community-based setting. We are aware of the financial costs of placing individuals in skilled nursing facilities and other custodial places. More important than cost, however, is that a home- and community-based approach gives the elderly and disabled a long-term care benefit which helps maintain their attachments to family and community while preserving their independence and dignity.

With that said, let me now offer some more critical observations. First, I would like the administration to explain to this committee the following contradiction in their long-term care initiatives: On the one hand, the centerpiece of the Health Security Act is the home- and community-based benefit for the disabled. On the other hand, it was not more than 6 months ago during budget reconciliation that the administration led the charge to repeal the Medicaid mandatory home- and community-based benefit. Of course, this was the Medicaid benefit that was passed into law during 1990 which CBO said would cost \$25 million when passed. However, because of a drafting error in the legislative language, its repeal during the 1993 reconciliation bill led to \$4 billion in savings. That is right, \$4 billion in savings. Therefore, I would like the administration's witness, Ms. Stone, to explain the logic and rationale behind the repeal of the Medicaid benefit while simultaneously recreating a much more ambitious entitlement for the same services in the President's health care reform act.

Second, the administration's plan gives the States complete authority to set up the quality and safety assurance standards. Well, Mr. Chairman, we remember the 1989 hearings and debates concerning the Florio "MR/DD" legislation and the Frail Elderly bill which specified detailed Federal quality assurance and safety standards based on the nursing home reform provisions of 1987. Just, yesterday, Mr. Chairman, you criticized Mr. Cooper for the



fact that his managed competition bill repealed all of the Medicaid statute, including nursing home reform standards. I am sure you will examine very closely the complete State deference to establish quality assurance standards.

Thank you.

[The opening statement of Hon. Gary A. Franks follows:]

#### OPENING STATEMENT OF HON. GARY A. FRANKS

Thank you, Mr. Chairman. Connecticut is very interested in seeing long-term care insurance being adopted as a more humane way of preparing and paying for long-term health insurance. Long-term care insurance allows an individual to continue their standard of living without having to sell off all of their assets if a time comes where the individual will need more intensive long-term care.

Long-term care insurance gives people the chance to plan ahead for the future and make legal and financial arrangements. It allows the individual to stay at home longer.

People are living longer than their previous ancestors, we need to encourage individuals to plan ahead for the longer lives they will be living. It is a shame that people save all their lives and end up spending it all for nursing home care.

Connecticut has developed the Connecticut Partnership for Long-Term Care. It is a joint public-private program which encourages individuals to plan for their long-term care needs by purchasing insurance protection in an amount equal to the amount of assets he or she wishes to protect. If and when an individual exhausts insurance benefits, the individual can apply for Medicaid and each dollar that the insurance policy has paid out in accordance with State policy will be subtracted from the assets the individual still has to that those assets would not be recognized or considered in determining the individual's eligibility for Medicaid.

The State of Connecticut is currently involved in a 6-year demonstration project. Connecticut is the first State to implement such an ambitious initiative to make long-term care insurance benefits available to many of its residents by combining private insurance with State Medicaid funds. The project will also sponsor six special studies ranging from surveys of individuals denied insurance or dropping coverage, to a survey of recent nursing home admissions and the collection of baseline information on those newly insured. Because this project is intended to inform the national debate over how to finance long-term care, the demonstration will include a process evaluation and examination of how the partnership affects the demand for insurance and utilization of long-term care.

I comment the President for wanting to strengthen the Government's role in the regulation of long-term care insurance.

Mr. WAXMAN. Our first witness at today's hearing is Dr. Robyn Stone, Deputy Assistant Secretary for Disability, Aging and Long-Term Care Policy for the Department of Health and Human Services. This is Ms. Stone's first appearance before the subcommittee. We are pleased she could join us.

I want to thank you for your participation today. We have already received your written statement, which will be included in the record in full. Now what we would like to ask you to do is to take no more than 5 minutes for your oral presentation.

#### STATEMENT OF ROBYN I. STONE, DEPUTY ASSISTANT SECRETARY OF AGING, DISABILITY, AND LONG-TERM CARE POLICY, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY MARY HARAHAAN, DEPUTY ASSISTANT

Ms. STONE. Thank you, Mr. Chairman and members of the committee. I am, by the way, accompanied by Mary Harahan, my deputy who is here to answer questions.

Thank you for inviting me to appear before you today to talk about long-term care. The inclusion of long-term care in the Health Security Act is concrete recognition that the long-term care needs of people with chronic illness and disability, a ventilator-dependent

child, a young man born with mental retardation, an elderly person with Alzheimer's disease, the survivor of an automobile accident, are as important for this Nation to address as the health needs arising from acute illness or injury.

The constituency for long-term care reform is a significant one. It includes many of our Nation's senior citizens, for older people have the highest probability of becoming disabled toward the end of life. It includes at least 10 million family members and friends of older persons and countless other family members of younger people with disabilities who experience caregiving responsibilities firsthand as they respond to the long-term care needs and problems of their loved ones.

It also includes 12.6 million people of all ages who, as a result of a disability, require some help to carry out routine activities of daily life.

Finally, it should include all of us, for anyone of us on any particular day or any of our children could become disabled as a result of an accident or chronic illness.

Long-term care in America today is at best a patchwork of financing and delivery systems frequently piggybacking on programs that were not designed to deliver chronic care. At worst, it is not there at all when people need it.

Long-term care is and must be a part of the health care continuum. It is not coverage for maids and butlers and other household staff. On the contrary, long-term assistance for many is the vital link that keeps people living at home. In fact, without long-term support at home many people turn to higher cost institutional care.

The Health Security Act takes both strides to create a plan that makes sense for people when they face the dilemma of needing long-term care. Importantly, the plan is prudent. It is carefully targeted at people with the highest level of need, people who are least likely to be able to make due only with family care.

We recognize that our available resources will not permit us to do everything. The Federal budget is capped and the financial liability of Federal and State government is limited. It will bring health and hope to millions of Americans without breaking the bank.

While a significant component of the long-term care program is a major new expansion of home- and community-based services, the plan also liberalizes Medicaid nursing home requirements, provides tax credits to help defray the costs of personal assistant services for working people, establishes Federal regs, consumer education and tax incentives for private insurance, and provides demonstration dollars to explore how to better integrate acute and long-term care services.

Since long-term care insurance was addressed in a previous hearing, I will focus the remainder of my remarks on the home- and community-based care program and the nursing home provisions.

The new home- and community-based care program offers highly individualized services tailored to the unique needs of people with severe disabilities. Eligibility is based on a person's level of function or cognitive impairment, with no limits by income or type of disability.

The new long-term care program is a Federal-State partnership. The Federal contribution is generous, 28 percentage points higher on average than the current Federal Medicaid match rates with the upper limits set at 95 percent. The high match rate is intended to encourage all States to participate.

This is a freestanding program, separate from Medicaid, Medicare and the health alliances, so States have the flexibility to build on the most creative practices of their communities and design packages that meet consumers' needs.

Each State must guarantee that every person has been carefully assessed and has an individualized plan of care. In addition, each State must offer personal assistance services, although every participant may not use this particular service.

In addition, States are required to have something somewhere in their service menu to address the needs of each category of eligible individuals. Beyond that, States are encouraged to include whatever services can best accomplish this, whatever people need to lead successful lives at home.

In addition, the program allows States to offer consumers cash or vouchers, instead of services permitting those who want to take on the responsibility of controlling their own services to do so. The legislation establishes a national budget for the new program. Although there is no individual entitlement to services, the budget was estimated as if there were. It is based on the cost of providing an adequate level of service to the eligible population and then it is capped.

There is also a sliding fee scale for consumers above 150 percent of poverty to pay a portion of the cost of services under this program. The funding for this program will be phased in incrementally over 7 years starting in 1996. Over the first 5 years, the Federal Government plans to spend \$56 billion for this program. The exact funding levels are specified in the legislation. The funding for the program is not discretionary. It is entitlement to States.

Let me very briefly in about another second just quickly describe the Medicaid nursing home improvements because they are an important part of the plan.

The plan also takes a series of steps to strengthen the resource protections of the Medicaid program for nursing home residents. All States will be required to establish medically needy eligibility criteria. Also the amount of income that nursing home and other institutionalized residents may keep for their personal needs will be raised from \$30 to \$50 per month. Finally, States will be allowed the option of increasing the level of assets that unmarried residents may retain from \$2,000 to \$12,000.

Mr. WAXMAN. Thank you very much for your testimony. I know you haven't completed reading it but everything is going to be in the record so we will have all of that in there.

Ms. STONE. Thank you.

[The prepared statement of Ms. Stone follows:]



## STATEMENT OF

ROBYN I. STONE, Dr.P.H.

DEPUTY ASSISTANT SECRETARY OF AGING, DISABILITY,  
AND LONG-TERM CARE POLICY

OFFICE OF THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION

Mr. Chairman and Members of the Committee:

Thank you for inviting me to appear before you today to talk about long-term care. From the outset of the health care reform debate, the President and the First Lady have made long-term care an essential component of their commitment to comprehensive health care. The inclusion of long-term care in the Health Security Act is concrete recognition that the long-term care needs of people with chronic illness and disability...a ventilator dependent child, a young man born with mental retardation, an elderly person with Alzheimer's disease, the survivor of an automobile accident...are as important for this nation to address as the health needs arising from acute illness or injury.

The constituency for long-term care reform is a significant one. It includes many of our Nation's senior citizens, for older people have the highest probability of becoming disabled toward the end of life. It includes at least 10 million family members and friends of older persons and countless other family members of younger people with disabilities who experience care-giving responsibilities first hand as they respond to the long-term care needs and problems of their loved ones. It also includes 12.6 million people of all ages who as a result of a disability require at least some help from others to carry out routine activities of daily life. Finally, it should include all of us... for any one of us on any particular day or any of our children could become disabled as a result of accident or chronic illness.

In short, for the elderly, for younger individuals with disabilities, their families and other people who care for them - for each and every one of us - long-term care reform is not expendable. It is a vital piece in solving the health care puzzle. Without basic ongoing supports to live in the community, a person with a severe disability might never get as far as exercising his or her right to universal health care coverage.

**THE LONG-TERM CARE PROBLEM**

Today I will tell you about the growing long-term care problem, explain our belief that health care reform is not complete without a long-term care component, and tell you about our proposed plan for tackling long-term care reform.

What would you do if you or a member of your family were suddenly not able to take care of themselves...to feed themselves or prepare meals, bathe, go to the bathroom, dress themselves, get in and out of bed, shop for food, manage their money, take medications...unless someone were there to help them. If you were married to such a person, and if you did not have to hold a paying job, you might be able to manage. But suppose you did



have to work, or your parent lived 3,000 miles away or you yourself were disabled or had an illness that prevented you from providing assistance...then what?

You would do what the vast majority of people in this country do now in such a situation--make do the best you can with informal care...purchase extra help to the extent you could afford, or do without. Why? Because if you turned to the obvious places that you would turn to if you experienced an acute health problem -- private health insurance, Medicare, the government...you would find precious little.

Most people are surprised to find that Medicare, which provides substantial coverage for acute health services, offers only limited, post acute support services to help beneficiaries get back on their feet. Similarly, even the best private health insurance policies provide virtually no long-term care. The only government program with significant long-term care benefits--the Medicaid program--is targeted to the poor, requiring many to become impoverished before qualifying for help.

In addition, Medicaid funding has been, and continues to be, significantly biased towards institutional care. In 1993, almost 85 percent of Medicaid long-term care expenditures were for institutional care. Further, despite increases in Medicaid home and community care spending, access to Medicaid home care services varies tremendously across States. So even though the overwhelming number of people with long-term care needs prefer services in their own homes and communities, these services are not universally available even to very poor people. In fact, in some sections of the country, you cannot obtain publicly funded home care no matter how poor or how much in need you are.

Long-term care in America today is, at best, a patchwork of financing and delivery systems, frequently piggybacking on programs that were not designed to deliver chronic care; at worst it is not there at all when people need it.

#### **HEALTH CARE REFORM MUST INCLUDE LONG-TERM CARE**

Long-term care is part of the health care continuum. No one questions the right to treatment for an acute health problem -- setting a broken leg, putting a cast on the leg, and following through with the necessary medical care to fix the leg. Yet long-term care is often misperceived as an extra service, almost a luxury.

Long-term care is not coverage for "maids and butlers" and other household staff. On the contrary, long-term assistance for many is the vital link that keeps people living at home. In fact, without long-term support at home, many people turn to higher cost institutional care.

#### **THE ADMINISTRATION'S LONG-TERM CARE PACKAGE**

The Health Security Act takes bold strides to weave the threads of patchwork into a comprehensive tapestry that makes sense for people when they face the dilemma of needing long-term care. The plan respects the dignity of people who need support -- it is not means tested and does not discriminate by age. It honors the choices of individuals and their families. It offers public services and incentives for people who can afford to protect themselves against the high cost of long-term care.

Importantly, the plan is prudent. It is carefully targeted at people with the highest level of need, people who are least likely to be able to make do only with family care. We recognize that our available resources will not permit us to do everything. The Federal budget is capped and the financial liability of Federal and State government limited. It will bring help and hope to millions of Americans without breaking the bank.

While a significant component of the Long-Term Care proposal is a major new expansion in home and community-based care services, the plan also liberalizes Medicaid nursing home requirements; provides tax credits to help defray the costs of personal assistance services for working people with disabilities; and establishes Federal regulations, consumer education and tax incentives for private long-term care insurance.

#### **MAJOR EXPANSION OF HOME AND COMMUNITY CARE**

The new home and community-based services program offers highly individualized services tailored to the unique needs of people with severe disabilities. Eligibility is based on a person's level of functional or cognitive impairment, with no limits by income or type of disability. Because people of all ages are equally eligible, this program goes a long way toward promoting an equitable intergenerational division of the long-term care pie.

Who will be eligible? The goal was to define -- across disability categories and age lines -- people with the most significant needs. The four mandatory eligibility categories include:

- people who need hands-on or stand-by assistance or cuing or supervision to perform three of five activities of daily living (eating, bathing, dressing, toileting, and transferring);
- people with severe cognitive or mental impairments;
- people with severe mental retardation; or
- children under six who have chronic disabilities and would otherwise require hospitalization or institutionalization -- after age six, children's eligibility is measured using the other three criteria.

Based on these criteria, it is estimated that approximately 3.1 million people will be eligible for this program; 71% or 2.2 million will be over age 65.

#### **FEDERAL STATE PARTNERSHIP**

The new long-term care program is a Federal/State partnership. The Federal contribution is generous...28 percentage points higher on average than current Federal Medicaid match rates, with the upper limit set at 95%. The high match rate is intended to encourage all States to participate. The President wants to encourage the creation of a universally available home and community-based services program for all people with significant disabilities no matter where they live.

The new home and community program is a free standing program, separate from Medicaid, Medicare, and the health alliances, so States have flexibility to build on the most creative practices of their communities and design service packages that meet consumers' needs.

#### **BENEFITS AND SERVICES**

Each State must guarantee that every person who receives services has been carefully assessed and has an individualized plan of care. In addition, each State must offer personal assistance services, support in daily living activities -- although every participant may not use this particular service. States must also offer consumers the opportunity to direct their own services if they are able.

In addition, States are required to have something, somewhere in their service menu to address the needs of each category of eligible individuals. Beyond that, States are encouraged to include whatever services can best accomplish this -- case management, homemaker and chore services, home modifications, respite services, assistive technology, adult day services, habilitation, supported employment, home health...whatever people need to lead successful lives at home.

In addition, the program allows States to offer consumers cash or vouchers instead of services, permitting those who want to take on the responsibility of controlling their own services to do so. In the words of many disability advocates: "we are not cases and we don't want anyone to manage us."

#### **FINANCING AND BUDGET**

The legislation establishes a national budget for the new home and community services program. Although there is no individual entitlement to services, the budget was estimated as if there were; it is based on the cost of providing an adequate level of service to the eligible population and then it is capped. The new program is not funded to replace family caregiving. In fact, the budget assumes that family caregivers will continue their

support. There is also a sliding fee scale for consumers to pay a portion of the cost of services under this program, ranging from 10% of costs for those at 150% of the poverty level to 25% of costs for those above 250% of poverty.

The funding for this program will be phased-in, incrementally, over seven years, starting in 1996. Over the first five years, the Federal government plans to spend 56 billion new dollars for this program. The exact funding levels are specified in the legislation; the funding for the program is not discretionary, it is an entitlement to States. In addition, during the phase-in, the law permits the Secretary of the Department of Health and Human Services (HHS) to increase these specified amounts if the new program results in reductions in Medicaid home and community care expenditures for persons with severe disabilities.

#### **QUALITY**

Experts in the quality field have noted that one of the best ways to ensure that services are of high quality is to involve program participants and their families in the quality assurance process. Therefore, the President's plan, in addition to requiring States to develop and obtain Federal approval of a thorough system for assuring the health and safety of consumers, also requires that consumers be involved in every step of the design of the program, its implementation and its evaluation. To ensure consumer input, States must set up special consumer dominated boards who help design the program and monitor its implementation. The board is also responsible for assessing the consumer-responsiveness of the plan as part of the Federal approval of the State program.

#### **MEDICAID NURSING HOME IMPROVEMENTS**

The plan also takes a series of steps to strengthen the resource protections of the Medicaid program for nursing home residents. All States will be required to establish medically needy eligibility criteria -- to take medical expenditures into account in determining financial eligibility for Medicaid coverage of nursing home care. Also, the amount of income that nursing home and other institutionalized residents may keep for their personal needs will be raised from a minimum of \$30 to \$50 per month, making a real difference in the dignity and quality of life of many residents. Finally, States will be allowed the option of increasing the level of assets that unmarried residents may retain from \$2,000 to \$12,000.

#### **NEW WORK INCENTIVE TAX CREDIT**

Having a severe disability can be very expensive; it can cost so much to buy the personal assistance services, home and vehicle modifications, and specialized equipment, that many people with disabilities throw up their hands and ask: "Why work? It costs more to work than to stay home." What a terrible waste; an explicit vision in this plan is to help all members of the community, including those with disabilities, to bring their



talents and skills to the fore, to be productive, contributing members of their communities.

To accomplish this goal, the plan includes a 50% tax credit for persons with disabilities for out of pocket expenditures on personal assistance and related services, up to a maximum of \$15,000 per year (or earned income, if less). For a maximum credit of \$7,500. This tax credit phases out for persons with income between \$50,000 to \$70,000. People with disabilities welcome this new incentive to work. This provision also works well with the employment provisions of the Americans with Disabilities Act.

**IMPROVING LONG-TERM CARE INSURANCE; OFFERING INCENTIVES TO BUY**  
As we complete the solution to the long-term care puzzle, the final piece is a series of improvements to the quality and reliability of the long-term care insurance market and make it more affordable. Unlike acute health care, private insurance pays very little of the nation's long-term care bill. Many people would be able to protect themselves against catastrophic long-term care costs if affordable and high quality insurance products were available. If an employer-based group market can be created, the number of people who can purchase private insurance to protect themselves will increase even more.

The President's plan takes a variety of steps to improve the quality of insurance and make it more affordable. New Federal regulations will be developed, implemented, and enforced by the States. A new Federal matching grant program will be initiated to help States with enforcement of new standards. Grants will also be made available to States and national organizations to provide education for consumers about their risks of needing long-term care, as well as the pros and cons of various kinds of insurance products.

The new insurance standards will be developed by HHS, in consultation with a long-term care insurance advisory board of national experts, including representatives of the National Association of State Insurance Commissioners. The Federal standards will include: a required nonforfeiture benefit, an offer of inflation protection; limits on pre-existing condition exclusions; notifications of pending lapse and required reinstatement in the event of incapacitation; clear definitions of coverage and eligibility triggers; and rules regarding continuation and conversion of group policies. Federal standards governing the business practices of agents and insurers as well as penalties for noncompliance will also be included.

The plan also includes tax provisions that treat long-term care insurance by providing favorable treatment for certain qualified long-term care policies more like health insurance. Consumers will be allowed to exclude from taxable income the amounts

receive as benefits under qualified long-term care policies. In addition, the premiums paid for qualified policies may be deductible as an itemized medical expense. To promote the group market, employers will be able to deduct premiums paid for qualified long-term care insurance and employees will not be taxed on the value of the coverage.

#### **PERFORMANCE REVIEW**

Finally, the plan also includes a performance review -- an interim and final report card so we can check up on how the new public and private long-term care system is working, and identify areas for improvement. On a related note, there are provisions for a series of demonstrations studying various ways to integrate acute and long-term care.

#### **SUMMARY**

In summary, we face a crossroads. Left untouched, the problem of unmet long-term care needs will not go away and will only get worse as the population ages. It's a problem that is unalterably entwined with the problems in our health care delivery and financing systems. We must address it in that context and demonstrate our commitment to all Americans to meet a range of health and related needs.

Mr. WAXMAN. I want to start off the questioning and let me understand how this new program is supposed to operate. First, as I understand it, participation in this new program is purely voluntary on the part of the State. Second, from a financing point of view, the program is based on the Medicaid model that is a joint Federal-State effort in which the Federal Government matches the State's contributions at significantly higher rates than is currently the case under Medicaid. Unlike Medicaid, however, the total amount of the Federal contribution is capped at the dollar amounts specified in the legislation.

Third, States which choose to participate are required to provide services to four mandatory groups: One, people in need of assistance with certain activities of daily living, such as bathing, eating, dressing, toileting or transferring out of bed; second, people with severe cognitive or mental impairments; three, people with severe mental retardation; and four, young children with chronic disabilities who would otherwise require institutionalization. States may pick and choose what types of services these people may receive but they must provide some services to all four categories of individuals.

Now, let me ask you a series of questions about how this new program will actually operate. I know you expect all States to participate in this new program, but what is your backup plan just in case a State, for whatever reason, chooses not to participate? How are people in that State supposed to get the home- and community-based care they need?

Ms. STONE. First of all, Mr. Chairman, let me indicate that because the match rate is so high, substantially higher, 28 percentage points higher than the current Medicaid match rate, we fully expect all States to participate in the program. It will be able to draw down significantly more dollars basically serving even the same people that they serve today. So there is a tremendous incentive for them to participate in the program, even States that are currently doing very little in home- and community-based services.

I think it is also important to point out that Medicaid remains "as is" on the long-term care side. That is to the extent that States are currently participating in the personal care program, the Medicaid waiver program, and also providing State-only dollars, these will continue and folks may be served in those programs as well as in the new programs. So in essence we are talking about those programs as a safety net.

Mr. WAXMAN. And this is going to replace the Medicaid program or be in addition to it?

Ms. STONE. This is in addition to the Medicaid program.

Mr. WAXMAN. Let's assume that all States do in fact participate in the program. Let's also assume that for whatever reason the amount of dollars for this new program in a given year is not enough to provide services for all four of the mandatory eligible groups. What is a State supposed to do if that happens?

Ms. STONE. Well, first of all, we think that the amount of the funds provided should be adequate to serve the approximately 3.1 million people we have estimated who will be eligible for this program. This is the way that the budget has been calculated, and we believe that we would be able to serve all these folks adequately.

If funds provided were not adequate, there are a number of options that the States could take, including cutting back on services, or also limiting new admissions. But you must remember that they cannot cut back on the eligibility. All the groups must continue to be served, and again, remember that folks can also be served in the continuing Medicaid program and the State-only programs.

I would like to point out that we have got a whole variety of experience with States using capped programs. The State of Oregon is a perfect example of a very successful home- and community-based program that works within a cap that has been able to allocate resources very prudently and judiciously across a whole set of populations.

Mr. WAXMAN. If a State is forced to cut back on the services it has been providing because they just don't have enough money, let's say they decide to cut back on adult day care services, what happens to those individuals who have already been receiving those services? Are adult day care services just no longer available for new program participants or are these current beneficiaries just out of luck? Is the State required to continue the coverage even if they have to pay for it with 100 percent of State dollars?

Ms. STONE. Well, again, as I indicated, we believe that this is a generous budget and that we will be able to serve all of the eligible persons within the cap. If a State chooses to reduce services, my assumption would be that current persons receiving services would continue to receive those services and, again, would have access to adult day care services, for example, through the Medicaid program or through other programs such as title XX or the Older Americans Act.

Mr. WAXMAN. If those dollars——

Ms. STONE. If those dollars were available.

Mr. WAXMAN. If those dollars aren't paying for it, they are using this new program and they run into the cap and they don't have the money and they decide they have got to serve everybody in every category but this is something they have got to cut out, what happens then? The beneficiaries are out of luck? You don't think that it will happen but it could.

Ms. STONE. My sense is what would happen is that persons who are currently receiving services would continue to receive services and then persons who then became eligible for the program would probably not have access to adult day through that particular program.

Mr. WAXMAN. Thank you very much. Mr. Bliley.

Mr. BLILEY. Thank you, Mr. Chairman.

Ms. Stone, welcome to the committee, and as I said in my opening remarks, and I will repeat, I would like you to explain to this committee the following contradiction in the administration's long-term initiatives. On the one hand, the centerpiece of the Health Security Act is the home- and community-based benefit, but it was just 6 months ago that during budget reconciliation that the administration led the charge to repeal the Medicaid mandatory home- and community-based benefit. This Medicaid benefit that was passed into law during 1990 which CBO said would cost \$25 million when passed, however, because of a drafting error in the legislative area, its repeal during the 1993 reconciliation bill led to



\$4 billion in savings. That is right, \$4 billion in savings. So I would like you to explain the logic and rationale behind the repeal of the Medicaid benefit while simultaneously recreating a much more ambitious entitlement for the same services in the President's Health Care Reform Act.

Ms. STONE. The repeal of the personal benefit in the administration's proposals was not a repeal of the Medicaid personal care benefit. Rather, the administration's proposal corrected a drafting error that occurred in the previous reconciliation package. The administration's proposal reinstated the previously optional personal care benefit as an optional benefit. So that is really what occurred.

And I would also like to point out that we are not talking about an open-ended entitlement within this new program. This is a capped program. It is an entitlement to the States. It is not an individual entitlement program.

Mr. BLILEY. Thank you. Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Bliley.

Mr. Wyden.

Mr. WYDEN. Thank you.

Dr. Stone, it is a pleasure to have you, and you obviously have great qualifications for this assignment. Let me ask you first, if I might, about the question of budget caps and this program and its specifics in terms of its finding.

I think you are absolutely right. My State has shown that compassion and good service in home care can peacefully coexist with a budget cap if it is done properly, and our State has shown that for a decade, and I guess my question first with respect to the cap is, how is the cap indexed and adjusted for such things as growth in the over 75 population?

Ms. HARAHAH. We have started with the 1990 census, the growth changes between the 1980 and 1990 census. That is in the current formula and that will continue to be updated to reflect the changes in the over 75 population.

Mr. WYDEN. How would you deal with future changes in Federal law that would increase costs of providing long-term care?

Ms. HARAHAH. In terms of adjusting the cap?

Mr. WYDEN. Nursing home reform issues, that kind of thing.

Ms. HARAHAH. I think we have to look very carefully as the program is fully implemented in terms of whether the dollar amounts that we have calculated as the proxy for expenditures per person don't need to be adjusted, and that is built in as an evaluation into the program. It is possible that they would need to be adjusted in the out-years.

Mr. WYDEN. The reason I ask that, I very much share the concerns of Chairman Waxman with respect to the budget issue because I think a lot of the States are not as advanced as my State is. My State has shown it can do it. As I say, budget caps and good care in the home sector can coexist, but I think the chairman is right because a lot of other States are not so far advanced and we want to work with you on it.

Let me ask you about one other thing. We already have a fair number of fly-by-night artists in the home care field. Now we are going to set up a multibillion dollar program and I am concerned about what this bill does to deal both with the rip-off artists that

I think are going to move into this field, and also not just people who are genuinely corrupt, but what is going to happen if you have a poorly trained case manager, for example? These case managers are going to be the people out on the front lines making these critical decisions with respect to the kind of services that our parents and our grandparents are going to be getting and I am concerned that there are not enough checks in there, both on the kind of corrupt rascals that I think are going to get into this field, and some already are, and second, not just about corrupt people, but people who may mean well but are not properly training the case managers who are going to be the hub in this whole operation.

Ms. STONE. I think you have raised some very important questions with respect to quality assurance and monitoring and training and certification. As you know, we have left quite a bit of discretion to the States, given the fact that we already have a wide range of States that have been very successful in developing case management programs, in training case managers, and ensuring that home care providers are scrupulous and working within the law.

Our plan basically leads toward consumer input and consumer involvement as the major check and balance with respect to looking at the quality of how case management is performed and how providers do their jobs.

We have two advisory groups, one at the Federal level and one at each State level, which is comprised of at least 50 percent consumers. These consumers are involved from the development of the State plan all the way through the implementation and the evaluation of the plan, that is to say, they really are the nuts and bolts. They roll up their sleeves and work with the States in designing the plan and ensuring that providers are providing the care in a very scrupulous manner and that the case managers are trained in a way that they can make those kinds of allocation decisions.

Mr. WYDEN. What would happen if the case manager was just incompetent? How would the system root that out in a fast way so that senior citizens, vulnerable people in these programs weren't hurt?

Ms. STONE. Well, again, I believe, and we believe, that States have been very successful in monitoring their case—in setting up and monitoring their case management systems, and rather than prescribing at the Federal level how every State should deal with its case management system because there is so much variability across the States, we have built in this consumer input check to work with the States in ensuring that we will not have incompetent case managers.

Mr. WYDEN. Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Wyden.

As you might have noticed, the bells ringing indicate that we are being summoned to the House Floor for a vote. So we will take a recess to vote and come back as soon as we can.

[Brief recess.]

Mr. BROWN [presiding]. The committee is now back in session. The gentleman from Pennsylvania, Mr. Greenwood, will be recognized for 5 minutes.

Mr. GREENWOOD. Thank you, Mr. Chairman. I think now that the two freshmen on the committee are in charge, we ought to move the previous question, call up the bill and get things rolling.

I would like to ask you a question about the transition. I know you have addressed some of this already, but let me be specific with regard to constituents of mine who are mentally retarded adults, Medicaid eligible and in institutions now. Are you saying that, in fact, they are guaranteed service or are we assuming that is what the States would continue to provide coverage under the President's program in the transition years?

Ms. STONE. Yes. They are in an ICFMR? Is that what you are telling me?

Mr. GREENWOOD. That is right.

Ms. STONE. The Medicaid program remains as is on the institutional side. The phase-in is for this new home- and community-based care program.

Mr. GREENWOOD. How about a CLA, community living arrangement [CLA]? Would that also be—

Ms. STONE. That also continues.

Mr. GREENWOOD. So there would be no effect on that population?

Ms. STONE. To the extent that States are participating now, they would—they could continue to participate. The law does not change.

Ms. HARAHAHAN. We have also said in the new program that States must continue to serve their current Medicaid recipients at an appropriate level, so they cannot withdraw services from—and just, for example, serve only a subset of the population. This program is not an excuse to dump people and the bill language makes that clear.

Mr. GREENWOOD. OK. Now, with regard to the home-based community service which has the higher Federal participation. I believe that is probably the right way to go because to the extent that we can keep people in their homes and their communities, it is better for the client and better for the taxpayer. What safeguards are there in the program, though, to ensure that patients who in fact do need and require the institutional care aren't shifted to home-based or community care for State budgetary reasons?

Ms. STONE. There are no specific safeguards in the legislation, but, again, I want to reiterate that with respect to this plan and the new program, there is significant consumer input into the design of the plan and the implementation of the plan, and that, in addition to that, there will be—consumers will be able to look at what is happening with respect to the continuing Medicaid program, including the institutional side, and will be able to have input in terms of insuring that there is no inappropriate movement of folks who are in institutions into home- and community-based services just to draw down more dollars.

Mr. GREENWOOD. To what extent do family members have a choice to make? Suppose that my mother or father were in need of care. Further, suppose my wife and I believe we can't manage with our work schedules and so forth to care for him/her at home, even though he/she may be better served that way. He/she may not need institutional care. Where does the family's role come in?



Ms. STONE. Well, again, there is no Federal prescription in the bill. Basically these decisions are made at the State level. Families are clearly involved in the care planning process and the extent to which families can provide assistance in the home and are available to provide assistance in the home, they would be built into the care planning process with respect to the home- and community-based care part.

With respect to the institutional side, there is the option of being placed in an institution. The State would take into consideration the family situation, but choice is built into this plan.

Ms. HARAHAH. Could I just say one more thing about this, as someone who has faced this particular kind of decision with their own parent, and there are certainly circumstances under which when you have to go to work every day, you can't cope at home no matter what. But one of the great strengths of the President's home- and community-based services proposal is that it provides incentives to develop lots of different kinds of residential arrangements in addition to the nursing home sector that we already have. So we would think that—assisted living, for example, would be a kind of residential arrangement where this program would begin to help pay for services and people would have more choices about settings outside their home where their parents or their other relatives might be able to go if they had severe disabilities.

Mr. GREENWOOD. Thank you. Thank you, Mr. Chairman.

Mr. BROWN. Thank you, Mr. Greenwood.

The administration initially intended to require States to increase the level of asset protection for nursing home residents under Medicaid to \$12,000, my understanding was, and make this a Federal requirement. When the bill was introduced, currently the increased protection is a State option. First of all, why was that change made and are States going to change? How many States are going to exercise that option?

Ms. STONE. Well, the decision was made with respect to that provision to change it from a requirement to an option because of a lot of problems that the States had with an unfunded Federal mandate, and so the decision was made, therefore, to make it optional rather than a requirement, and, frankly, we do not have an estimate of how many States would take up this option.

Mr. BROWN. Do you have any guess as to—what logically does that option tell you?

Ms. HARAHAH. Probably not a whole lot.

Mr. BROWN. The gentleman from Connecticut, Mr. Franks.

Mr. FRANKS. Thank you, Mr. Chairman.

Ms. Stone, Connecticut and a few other States have worked hard to create a public-private partnership for long-term care, and I personally would like to see the State's plans, as well as—not only Connecticut, I think Indiana and California would have the same—I would like to see that continued under any health care policy change. So my question to you would be, where do you stand as far as the concept of a public-private partnership per the Clinton plan?

Ms. STONE. Well, with respect to a public-private partnership, we believe that this plan is in fact a public-private partnership. What we have done is to put together a package that develops a new home- and community-based care program using public dollars and



regulates very strongly and provides very important consumer education and tax clarifications and tax incentives for the development of a quality affordable private market for those who should be purchasing private insurance policies and want to prefund for their long-term care needs. So in that sense, we do see this as a very strong public-private partnership, being able to use both public and private dollars to try to meet the needs of a very desperate group of folks with very significant needs, some of them working through the public sector and some of them receiving services through the private sector. Also, Medicaid remains unchanged, and therefore the Robert Wood Johnson-type of programs that you were alluding to in Connecticut and several other States can continue.

Mr. FRANKS. Very good. Thank you.

Mr. BROWN. Thank you, Dr. Stone, for joining us.

The members of our next panel represent various consumer organization with a strong interest in long-term care. Orien Reid is a member of the National Board of the Alzheimer's Association, which is a member of the Long-term Care Campaign on whose behalf she is testifying today. Appearing on behalf of the Consortium of Citizens With Disabilities is Anthony Young; and representing the American Association of Retired Persons as a member of its board is Tess Canja.

I want to thank all of you for appearing before the subcommittee. We have received copies of each of your prepared remarks which will be included in full for the committee record. Please take no more than 5 minutes to summarize your comments, then the subcommittee obviously will have questions for you.

Ms. Reid, let's begin with your opening statement.

**STATEMENTS OF ORIEN REID, MEMBER, NATIONAL BOARD, ALZHEIMER'S ASSOCIATION, ALSO ON BEHALF OF LONG TERM CARE CAMPAIGN, ACCOMPANIED BY STEPHEN McCONNELL, SENIOR VICE PRESIDENT, ALZHEIMER'S ASSOCIATION; ANTHONY J. YOUNG, ON BEHALF OF CONSORTIUM OF CITIZENS WITH DISABILITIES, AND THE LONG TERM SERVICES AND SUPPORTS TASK FORCE; AND TESS CANJA, MEMBER, BOARD OF DIRECTORS, AMERICAN ASSOCIATION OF RETIRED PERSONS**

Ms. REID. Thank you, Mr. Brown. I am here today as a spokesperson for the Long-term Care Campaign and for the Alzheimer's Association, one of the lead organizations in the campaign. I am a member of the National Board of the Alzheimer's Association and the board of our Greater Philadelphia Chapter.

The Long-Term Care Campaign is a coalition of 137 national consumer organizations organized in 1987 to get long-term care into our health care system. Together, we represent more than 60 million Americans. I would like to submit a list of those member organizations for the hearing record.

The makeup of the campaign underscores a central truth about long-term care. This is not just an aging issue. It is a family issue, as I well know. One-third of all persons who need long-term care are children and younger adults, but regardless of the age of the person with the illness or disability, every person in the family is affected.

Our health care system now discriminates by disease and by disability. If you have a heart attack and need surgery or if you have cancer and need chemotherapy, the system recognizes your health care needs and insures them. But if your child has cerebral palsy, if you suffer a spinal cord injury, if you get Alzheimer's disease, the system abandons you because the type of health care you need, long-term care, is not provided in hospitals or doctors' offices.

We organized the Long-Term Care Campaign to change that system. From the very beginning, the chairman has been one of our strong allies. Now President Clinton has joined us with a far-reaching proposal for long-term care, and the President's proposal meets the essential needs. It starts in the right place with home- and community-based care. It provides a program for people with all kinds of illnesses and disabilities. It covers cognitive and mental impairments. It is consumer choice. It is a plan with consumer choice, and it is flexible. But I would like to tell you my personal story because I think it may help you understand best how families in our situation face long-term care needs.

I brought along with me a picture of my family. These are my children with me and my mother who had Alzheimer's disease. In 1988, she was diagnosed with the disease. At that point I was a single parent raising these two children who were young teenagers at that point, and she was supposed to come to Philadelphia and I was supposed to meet her at the bus station and she didn't show up. She didn't even remember that she was supposed to come.

For the next 3 years after that, I felt like I was living a nightmare. I was in the middle of a vise between trying to take care of my children, trying to take care of my mother, and trying to keep a full-time job. I am a reporter for CBS news, WCAU-TV in Philadelphia and I am paid decently but it is a very difficult job and it is very hard to take care of somebody with Alzheimer's disease no matter what you earn.

At that point my stepfather—my mother was living in Atlanta. My stepfather was 80 years old and there was a limit of to what he could do. For the next few months I spent time running back and forth, flying between Atlanta and Philadelphia, trying just to make sure that things got organized for them.

A short time later, my stepfather was diagnosed with pancreatic cancer. That was a nightmare in itself because it meant the day he went to the hospital, and I talked with my mother, I said, who is with you, and she said, nobody, and I knew she couldn't be there by herself, so I had to hire a home health aide immediately at \$11 an hour, 10 hours a day, to stay with her, and I managed this long distance.

My stepfather died within 6 months. The day after the funeral, I had to bring my mother to Philadelphia with me and I took her to work with me because I had no other choice. I needed to do that for a few days until I could arrange day care for \$32 a day. My mother was sick, but her insurance, nor mine, would pay for any of this. It almost wiped me out, totally taking money that I had saved for my children's education. I used it for my mother. I don't know how anybody could manage that.

Our whole family life was in chaos. I had to depend on my children to take care of my mother after school. I was—all of the jug-

gling I was doing finally came to an end in October of 1990 when I came home one day and my daughter said to me, Mom, this has just got to stop. My mother was normally a very sweet lady, but that particular day she had been chasing my son around the house with a coat hanger until he ran across the street to a neighbor's house for protection.

I had to do something right away and the only option I had was to move my mother into a nursing home, and I had to sign papers at that point saying that I would be responsible for her bills. My mother had been a secretary all of her life, all of her career. She only earned \$12,000 a year and that was not enough. That was just one-third of the cost of a nursing home. I had to pay the rest of that.

In all of this my children lost a part of their childhood. My son had serious problems in school. It meant that my daughter lost some money that I was saving for her for college, and we all wanted to take care of my mother, but we just needed a little help and the help wasn't there. Just a little help would have helped us so much for my mother and my children.

The program that the President is proposing would have been a godsend for us. It would have paid for enough help to help prevent the crisis that forced us into the nursing home. We still could have provided most of my mother's care, and I would have been willing and would have paid my fair share.

Members of the Long-Term Care Campaign and the Leadership Council of Aging Organizations recently released a midterm report card rating the various plans that are before Congress. I have that and I would like to submit that, too, for the record.

The bottom line here is that none of the other health care proposals before you, except the single-payer plan, does anything meaningful for long-term care.

One of the principles of health care reform President and Mrs. Clinton talk about is personal responsibility and they are right. We are all responsible for our loved ones and I didn't want to give up caring for my mother, but I had no choice. The system abandoned us. It abandoned my mother. It abandoned me, and most of all, it abandoned my children.

With health care reform, your committee has perhaps the most difficult and important challenge of our lifetime, but health care reform cannot accomplish its objectives. It will not be comprehensive, it will not provide health security for all Americans, and it will not contain costs unless it includes long-term care. All of the organizations in the campaign and all of the families in the 221 chapters of the Alzheimer's Association are prepared to work with you to make sure that happens. Thank you.

Mr. BROWN. Thank you, Ms. Reid.

[The prepared statement of Ms. Reid follows:]



STATEMENT OF ORIENT REID  
HOUSE ENERGY AND COMMERCE COMMITTEE  
SUBCOMMITTEE ON HEALTH AND ENVIRONMENT  
January 20, 1994

Thank you Mr. Chairman. I am here today as a spokesperson for the Long Term Care Campaign and for the Alzheimer's Association, one of the lead organizations in the Campaign. I am a member of the National Board of the Alzheimer's Association and the Board of our Greater Philadelphia Chapter.

The Long Term Care Campaign is a coalition of 137 national consumer organizations organized in 1987 to get long term care into our health care system. The Campaign is made up of organizations representing older Americans, persons with disabilities, women, veterans, nurses, church and labor union members. Together, we represent more than 60 million Americans. (I would like to submit a list of the member organizations for the hearing record.)

The Alzheimer's Association, as you know, is the national voluntary health agency that represents the interests of the 4 million Americans who have Alzheimer's disease and the families who care for them. We work through over 200 local Chapters in the 50 states, more than 2000 support groups and over 35,000 volunteers.

The makeup of the Campaign underscores a central truth about long term care. This is not just an aging issue. It is a family issue. It affects people of every age. One third of all persons who need long term care are children and younger adults. But regardless of the age of the person with the illness or disability, every person in the family -- parent, spouse, sibling, child, grandchild -- is affected.

We have a health care system now that discriminates by disease and disability. If you have a heart attack and need surgery, or if you have cancer and need chemotherapy the system recognizes your health care needs and insures them. But if your child has cerebral palsy, if you suffer a spinal cord injury, if you get Alzheimer's disease, the system abandons you because the type of health care you need -- long term care -- is not provided in hospitals or doctors' offices.

We organized the Long Term Care Campaign to change that system. From the very beginning, Mr. Chairman, you have been one of our strong allies. Now President Clinton has joined us with a far-reaching proposal for long term care.

#### The Clinton Plan for Long Term Care

The President's proposal meets essential principles of the Long Term Care Campaign:



- First, it begins in exactly the right place, with home and community care. The President's plan will turn the system upside down. Instead of forcing people into nursing homes - where no one wants to be -- his plan provides services in settings that are more humane, more appropriate, and for the vast majority of people less expensive.
- Second, it is a program for persons with disabilities of all ages and income, with protections for low-income families and cost-sharing for those who can afford to contribute.
- Third, it includes specific eligibility language to assure coverage for persons with cognitive and mental impairments as well as physical disabilities.
- Fourth, it provides consumer choice of services and providers.
- Fifth, it is flexible, so that services can meet individual needs, through personal assistance, day care, respite, home modifications, habilitation and rehabilitation, and services in community residential settings.

### One Family's Story

I would like to tell you my family story, because it may help you understand why the Alzheimer's Association and other organizations in the Campaign are so enthusiastic about the President's proposal.

In 1988, I was a single parent, raising two young teenagers in Philadelphia and working as a reporter with the CBS owned and operated station there, WCAU-TV. My mother and stepfather lived in Atlanta. Our lives changed forever that year. It was Labor Day weekend. My children and I were excited that my mother was coming to visit. We went to meet her at the bus station. She never showed up. I called her long distance and she didn't even remember that she was supposed to come. I told her, "Mother, something's wrong. I'm going to bring you here to find out what it is". A few weeks later, I finally got her to Philadelphia. She went through a thorough diagnostic evaluation. The diagnosis was Alzheimer's disease.

For the next three years, we lived a nightmare. I felt like I was in a vise, with the screws just turning tighter and tighter between trying to raise my children, care for my mother, and keep a full time job.

My stepfather was 80 years old. There was a limit to what he could do. I flew between Philadelphia and Atlanta just trying to get things organized for both of them. I can't begin to tell you how expensive that was. A short time later, my stepfather

was diagnosed with pancreatic cancer. My mother couldn't stay alone so I paid an aide \$11 an hour for 10 hours a day to stay with her while he was in the hospital. He died within 6 months.

The day after his funeral, I brought Mother to live with us. I even had to carry her to work with me a few days until I could arrange for day care. When I finally found it, it cost \$32 a day.

My mother was sick, but neither her insurance nor mine paid for any of her care. It almost wiped me out, taking all of the money I was saving for my children's education. I had a good job and was paid decently. But no one can afford to handle this kind of expense over a long haul. I can't imagine how an elderly couple on a fixed income would manage. Or how a parent working a minimum wage job could manage.

My family's life was in chaos. I had to depend on my children to look after my mother when they came home from school. All of the juggling I was doing fell apart one afternoon when my daughter met me at the door and said, "Mom, this has got to stop!" My mother, who had always been a sweet adorable lady, had terrorized my son, chasing him around the house with a coat hanger until he ran to a neighbor's house for protection.

I had to do something right away. The only option we had was to put her in a nursing home. It cost \$100 a day and I had to sign papers saying I would be responsible for the bill. After working all her life as a secretary, my mother's pension and Social Security came to \$12,000 a year -- not even a quarter of the nursing home bill. She could have qualified for Medicaid, but there was a two-year wait for a Medicaid bed. We couldn't wait.

My children lost a part of their childhood. My son had serious problems in school. My daughter lost the money I was saving for her college education. We wanted to care for my mother. But we needed help -- and the help just wasn't there. Just a little help would have made such a difference for my mother and for my children.

The program the President is proposing would have been a Godsend for us. It would have paid for enough help to prevent the crisis that forced us to the nursing home. We still could have provided most of Mother's care. And I would have paid a fair share of the cost of the help we received.

#### Alternative Proposals Ignore Long Term Care

Members of the Long Term Care Campaign and the Leadership Council of Aging Organizations recently released a mid-term report card on long term care, rating the various plans before

Congress. I would like to submit that report card for your record. The bottom line is, none of the other health care proposals before you, except for the single payer plan, does anything meaningful about long term care.

Most of the plans would rely on private insurance. That just will not work. With monthly premiums of \$200, \$300 or more for reasonable coverage, it is just too expensive for most families. Tax incentives might make it affordable for a few more, but most families would still be priced out of the market. Is that really the way we want to spend the next tax dollars for long term care? Especially when companies will not sell policies to people who are most likely to need care. And most policies will not begin to cover all of the care a person with a long term illness or disability will need.

My mother would not have been able to purchase long term care insurance and I could not have bought it for her, even with tax incentives and better standards. And with two children to put through college, I certainly could not afford such insurance for myself.

There is one proposal on the table, the Cooper bill, that would take a huge step backwards. It would take away what federal support there is now for long term care. Imperfect as Medicaid is -- it at least provides some safety net for low-income families. Under the Cooper approach, states could use any money they "save" out of health reform to replace the federal dollars they will lose. But there are at least three problems with that assumption.

- First, there is no guarantee states would use the money for long term care -- and there would be a lot of worthy competition for the dollars -- education, roads, jobs, for example.
- Second, because the bill does not provide universal coverage for basic health care, there are still going to be a lot of uninsured families and someone is going to have to pay for their care -- there will be a lot of pressure on the states to pick up the pieces.
- Third, even if every "freed up" dollar was spent for long term care, at best there would be enough money to sustain current Medicaid long term care benefits -- leaving families like ours right where we were, with no help at all.

#### Long Term Care as Cost Containment

We do not ignore the central concern Congress must have about cost. The President is proposing significant new expenditures for long term care. But there is mounting evidence

that such expenditures will yield important savings, in nursing home costs and in avoidable hospital expenses.

- You will hear later this morning about Wisconsin's community options program which has led to a dramatic reduction in nursing home bed use in that state, at the same time bed use was rising 24% nationally.
- According to the National Institute of Medicine, delaying admissions to nursing homes by just one month would save \$3 billion a year. Wisconsin proves this is an achievable goal.
- In the Independent Living for Seniors program in Rochester, New York, use of adult day care has cut hospital utilization by participants in half.
- A study released this summer found that costs of paid care for persons with Alzheimer's disease in a nursing home are three and a half times more than the costs of paid care for a person living at home. That is because families continue their central role as caregivers when they get help, instead of turning the whole job over to paid providers.

Mr. Chairman, one of the principles of health care reform President and Mrs. Clinton talk about is personal responsibility. They are right. We all have to take responsibility for our own health and the health of the people we love. I didn't want to give up caring for my mother. But I had no choice. The system abandoned us. It abandoned my mother. It abandoned me. And most of all, it abandoned my children.

Mr. Chairman, with health care reform, your Committee has what is the perhaps the most difficult and important challenge of our life time. But health care reform cannot accomplish its objectives.... It will not be comprehensive.... It will not provide health security for all Americans.... And it will not contain costs.... Unless you include long term care.

All of the organizations in the Campaign, and all of the families and 221 Chapters that make up the Alzheimer's Association are prepared to work with you to make that happen.



Mr. BROWN. Mr. Young, your opening statement, please.

### STATEMENT OF ANTHONY J. YOUNG

Mr. YOUNG. Good morning, Mr. Chairman. I am Tony Young, Director of Residential and Community Support Services with the American Rehabilitation Association. I am appearing before you today as a consumer of long-term services and as a representative of the Consortium For Citizens With Disabilities, a coalition of over 100 national organizations representing consumers and providers of services to people with disabilities.

I have several points to make this morning, but the one overriding message that I want to convey to you is this: Health care reform that does not include provisions to address the urgent need for long-term service is not real reform. It is critical that reform proposals address both the acute and long-term service needs of Americans with disabilities of all ages.

I can tell you from personal experience that effective long-term services can have a profound effect on a person's life. As an individual who is a C-4 quadriplegic, I require assistance with many activities in my life, including bathing, dressing, eating, toileting, transferring and other tasks. Before I was able to arrange personal assistance, I spent my time watching television and sleeping. There were many days when I never got out of bed because my family did not have the energy to help me in both mornings and evenings after working all day.

With personal assistance, I have been able to complete a degree in business administration and to work in a series of jobs which have developed into a satisfying career. I have an active social life and participate in a variety of community activities.

The lack of effective long-term services frustrates the efforts of individuals with disabilities to live in the community, to find jobs, to receive employment training and do all the different things that makes one a participating member of society. An effective long-term services program would assist providers of residential, vocational, habilitation, rehabilitation, and medical services to enable people with disabilities to achieve their chosen goals.

There are many strengths to the President's proposal. First, the eligibility criteria do not exclude people by categories such as age, disability or income. This is a major improvement in eligibility determination approaches.

The proposal also calls for a broad range of long-term services. Individuals with families have diverse needs for long-term services. Comprehensive, flexible long-term services are essential in order to meet these diverse needs to preserve families and to support people in their own homes and communities. The President's proposal does not require individuals and families to impoverish themselves in order to receive long-term services.

The introduction of a disability into a family means substantial changes. One of those changes should not be the forced divestiture of all resources. No family wants anymore than to be able to help their family member stay at home without being an undue burden on the family structure.

The proposal maximizes the empowerment of people with disabilities by infusing consumer control into all levels of the long-term

services system. Individuals with disabilities and their representatives will constitute a majority of both the Federal and State advisory committees that will design and monitor the new systems. Consumers will be able to choose their own services and service providers as well as to direct them.

There are substantial investments in productivity in the President's proposal. The tax credits for working individuals with disabilities will be the difference for many people that will enable them to work. They cannot afford to work now due to the cost of the personal assistance required for them to hold jobs. This program should encourage individuals with disabilities to be productive members of society.

There are a number of improvements or refinements to the Clinton proposal that CCD would like to suggest. As currently drafted, the severity requirements for eligibility will not cover many people who desperately need long-term services. We are especially concerned that the eligibility criteria for persons with cognitive and mental impairments and children with disabilities be appropriate to capture those who most require services.

Another improvement involves the range of services that State programs are required to offer. States must be required to demonstrate—show conclusive assurances that all needs of eligible individuals with disabilities can be met within their State plans.

The current schedule outlined in the draft bill raises several problems. CCD recognizes that the individuals with disabilities should participate in the financial possibility for long-term services, but there must be a cap for low- and middle-income families on long-term service, out-of-pocket cost, similar to those placed on out-of-pocket costs for acute care.

None of these problems are insurmountable. CCD looks forward to working with the Congress to make this program the best system possible. CCD will submit specific legislative language to address these issues within 2 weeks.

All individuals with significant disabilities have one thing in common, the promises of the Americans With Disabilities Act, for inclusion in the mainstream of American society are meaningless to us without effective long-term services. Many of us would never be able to contribute to the Nation's economic, cultural or spiritual growth without long-term services. You can make the—you can ensure that the promises of the ADA are kept for people with significant disabilities by making long-term services an indispensable part of the health care reform.

Thank you for this opportunity. I would be happy to answer any questions you might have.

Mr. BROWN. Thank you.

[Testimony resumes on p. 309.]

[The prepared statement of Mr. Young follows:]

TESTIMONY OF ANTHONY J. "TONY" YOUNG  
ON BEHALF OF THE  
CONSORTIUM FOR CITIZENS WITH DISABILITIES  
LONG TERM SERVICES AND SUPPORTS TASK FORCE

Good Morning, Mr. Chairman. I am Tony Young, Director of Residential and Community Support Services at the American Rehabilitation Association, formerly the National Association of Rehabilitation Facilities. I appreciate this opportunity to appear before you today as a consumer of long term services and professionally on behalf of ARA and the Consortium for Citizens with Disabilities (CCD). ARA is the largest national trade association representing providers of medical, vocational, and residential services to individuals with disabilities.

CCD is a working coalition of over 100 national consumer, advocacy, provider, and professional organizations which advocate on behalf of people of all ages with physical, mental, and sensory disabilities and their families. Since 1973, CCD has advocated for federal legislation, regulations, and funding to benefit people with disabilities. My testimony today is presented on behalf of the undersigned members of the CCD Task Force on Long Term Services and Supports.

As an individual with quadriplegia at the C-4 level I require assistance with many activities in my life, including assistance with bathing, dressing, eating, transferring, travel, shopping, laundry, housekeeping, and taking medications. These services form the foundation onto which I build my life of work and leisure.

These are critical services for me and for many other people with severe physical disabilities. However, in designing a national long term services program, Congress must keep in mind that the causes and consequences of chronic disabilities are highly varied and require significantly different responses on the part of the service delivery system, depending on the nature and extent of the individual's disabling condition as well as the surrounding circumstances of his or her life. An infant with complex medical needs in combination with severe cognitive disabilities will require a much different constellation of services and supports than someone with needs similar to mine. Likewise, a young adult with severe and persistent mental illness needs access to an array of continuing and intermittent supports that would be inappropriate in the case of an elderly individual who no longer is able to perform basic functions of daily living. Formulating an effective national long term service policy, therefore, must begin with an appreciation of the diversity of needs represented among the millions of Americans with severe disabilities and proceed to the creation of financing mechanisms and service delivery strategies that fully accommodate these differences.

#### PERSONAL SITUATION AND SYSTEMS ISSUES

All of my personal needs are not met by the current service system. While there are some services and supports available, the major funding source -- Medicaid -- is not available to me unless I impoverish myself. Many states severely limit the duration and scope of personal care that their Medicaid programs will purchase. Furthermore, even if a state has a Medicaid home and community-based waiver program, it may be targeted to elderly individuals or to people with specific types of disabilities and not available to individuals with other disabling conditions. After I became disabled, I became eligible for Medicare after two years but Medicare does not cover any ongoing personal assistance or rehabilitation. These gaps must be filled.

It is fair to say that personal assistance services have not simply influenced my lifestyle; they have enabled me to have a lifestyle. Without the education, employment, mobility, and freedom of choice that personal assistance services have brought to my life, I would have a bleak existence and an even bleaker future. Consider the differences with and without personal assistance services.

Without personal assistance services I spent the majority of my time watching television and sleeping. I watched television because it was my only companion, as I was unable to get out to see friends and meet new people. I slept to escape the boredom of watching television. There were many, many days when I never got out of bed because my family did not have the time or the energy to help me in both the mornings and the evenings, especially after working all day.

The days when I did get up were short days, partly because I had to do so between family members' work schedules, and partly because I didn't get up enough to build up my endurance. Even though I never worried about getting food, drink and medications, there wasn't much more to my life than eating, sleeping, and watching television.



With personal assistance services I have been able to complete a degree in business administration and to work in a series of jobs which have developed into a satisfying career. I manage to pursue an active social and advocacy life, and I have a reasonable expectation that these activities will continue. I find myself thinking of the future in terms of the next few years instead of the next few days. I find myself now living in a world of potential rather than a world of despondency. There is the potential of a home of my own, and a family of my own.

This is not to say there are not problems with my personal assistance arrangements. The current system of long term services does virtually nothing for me. I am not eligible for any subsidies because of my income level. The current tax structure is limited to medical deductions, which are subject to a 7.5% Adjusted Gross Income exclusion, and deductions for personal assistance at the worksite.

Therefore, my family and friends must still spend too much time helping me, because I can only afford about one quarter of the long term services time I really need. I now pay about \$600 a month for 60 hours of services, an average of about two hours per day. The rest of the support time I need, about six hours per day, is provided through a combination of family, friends, and my far-sighted, enlightened, supportive employer. There is no way I could personally afford the full cost of my long term services, which can be as high as \$2,000 a month. In addition, my private insurance covers rehabilitation services and therapies if I need them. My insurance also covers my equipment, such as my wheelchair, my braces, and training to use this equipment properly.

With this system I often receive inadequate personal assistance services in the form of too few hours of services, leading to health problems such as pressure sores from lack of pressure releases, or urinary tract infections from a lack of fluids (I can't use the bathroom because I don't have the assistance I need, therefore I simply don't drink any fluids). Sometimes I am forced to employ providers with inadequate personal assistance services skills in order to have someone to cover enough hours of basic services such as food preparation and assistance with eating. In addition, I cannot offer my personal assistance services employees typical benefits, including sick and annual leave, or health insurance, rendering it very difficult to recruit and retain quality personal assistance services providers.

I choose to hire my own attendants for certain reasons. People can receive attendant services through home health care agencies and often are required to do so if the services are being paid for by Medicaid. However, if you are paying for services out of your own pocket, agency-run programs are often costly and do not permit full consumer direction.

Simply locating good personal assistance services workers is a daunting task, as is keeping them once they are located. It is difficult for individuals working alone to locate reliable, competent employees to fill personal assistance services positions. I do not have the authority or the resources to investigate the backgrounds of potential personal assistant services providers who answer requests for applications. Too often the only way for me to judge the true character of a personal assistance services provider is to allow the provider into my home and monitor the individual's performance. This is an inappropriate, dangerous procedure.

I have attempted to work with various agencies, including an Area Agency on Aging and a Center for Independent Living, in order to recruit workers. Efforts to create registries of potential workers have had limited success, at best. These agencies, despite their best efforts, do not now have the resources to maintain a system that could offer pools of eligible workers, emergency workers, or orientation programs for these workers. A better, more comprehensive system must be established.

I manage despite these problems, although at times I feel as though I am operating a personnel department in order to conduct my professional and personal life. Maintaining an adequate personal long term services system consumes a great deal of my time and energy, in addition to money. I am fortunate that I have a job which pays me enough to afford what I can, and that I have an employer, family, and friends that help to make up the staggering difference. Few others are as fortunate as I am. Given the age of some of my family members, my good fortune will end in a short time as well.

This is my personal experience with long term services. Other individuals with different disabilities will have different service needs, hour requirements, and circumstances to contend with. A person with a cognitive disability might need several hours per week of assistance in managing their money and making



financial decisions. In another instance, a person might need a reader, sign language interpreter, or oral interpreter to communicate with landlords, relatives, or shopkeepers.

People with other long term support needs, such as individuals with mental retardation or developmental disabilities or people with serious mental illness, typically receive their services through a variety of specialized provider agencies. Many of these community providers serve individuals who are receiving Medicaid-reimbursable services. However, access to these services depends on the state you live in and your level of income and resources. Again, Medicaid services are limited to individuals with very low incomes who are among the most vulnerable. But I would prefer not to make myself more vulnerable by becoming poor just to receive services. As I said, I want to be productive and live my life.

Many people with disabilities are in jeopardy of being placed in a long term care institution, such as a nursing home, psychiatric treatment facility, or a residential center for people with developmental disabilities. The existing federal policy bias toward using institutional care when a person has a particular diagnosis or may need a high level of service must be reversed. I know I would never voluntarily choose this option, as most others would not.

The lack of an effective long term services system raises additional systems issues as it complicates the delivery of residential, vocational, habilitation, and medical services. Consumers are hampered in their efforts to achieve their life's goals because they do not have the services and supports necessary to access needed services from providers in the community. Although the symptoms of this problem manifest themselves in different ways for different providers, the underlying cause of each symptom is the lack of a solid foundation of long term services.

Consumers needing residential services and supports face the most flagrant of the problems. In their efforts to locate community living arrangements, individuals and providers must struggle with funding sources that require burdensome levels of resident supervision, and service requirements which force the creation of miniature institutions rather than homes. These same programs may be unable to compensate provider personnel with a living wage and with benefits commensurate with the professional level work they perform, resulting in great difficulty in recruiting quality personnel, and an unacceptably high turnover rate among staff. These and other restrictions conspire to keep some residential services unacceptably expensive, inappropriately institutional, and inordinately difficult to deliver.

Individuals with disabilities needing vocational services are hampered as well. The most obvious impediment is a lack of transportation, in the form of drivers and companions to assist in the use of public transit, which prevents participants from traveling to the worksite. Less obvious, often because this situation is not reported due to its embarrassing nature, is that people with severe disabilities have no one to help them get them out of bed, washed, dressed, and into their preferred mobility aids. This barrier not only prevents people with severe disabilities from getting to work, but also forces individuals to either inappropriately rely on volunteers, coworkers, and even supervisors in order to eat lunch and use the bathroom while at work, or to try to do without food and drink all day long.

In situations where consumers receive acute rehabilitation, physical and occupational therapy, and related services, they often face an impossible task when attempting to complete the final step in returning to the community. They face the dilemma of returning to a community setting without adequate long term services or staying inappropriately in the acute or chronic care facility. Without appropriate support services, returning to the community often results in the person developing additional health problems, which increases the chance of the person obtaining a secondary disability, adds severe stress to the family, and drastically reduces the individual's quality of life. Remaining in an acute or chronic care facility results in unnecessary costs, an inappropriate living situation for an individual who is no longer ill, and prevents an individual in true need of acute or chronic care services from receiving those services. Appropriate community supports would prevent these negative outcomes.

#### **VARYING LONG TERM SERVICE NEEDS: SOME EXAMPLES**

The following are brief descriptions of various people with disabilities of all ages and the circumstances of their lives. Long term services reform as a part of the health reform package will be vitally important to them all.

o A ten year old boy in Connecticut who required 24-hour a day ventilator support lived in a hospital for the first three years of his life. With intensive respiratory interventions and exercise, he has been able to reach the point where he lives at home with his family, attends public school in the fifth grade, and requires ventilator support only at night while sleeping. Continued access to such support will be vital to him.

o A twenty-eight year old man lives in a nursing home in Virginia because he is unable to receive the combination of nursing services, personal assistance services, and companion services which he needs to remain in his home. As a result of multiple gunshot wounds, he is paralyzed from the neck down, requires a ventilator, and uses a motorized wheelchair controlled by a mouthstick. His marriage has ended and he is now able to see his two children, ages seven and four, in short visits spread over the year, totalling only about 48 hours a year. With proper personal assistance and other long term supports, he could live in his home community and participate more fully in the lives of his children.

o A young woman, age 24, with cerebral palsy and mental retardation has benefitted significantly from the Medicaid community supported living arrangements services program. She lives in her own apartment with a roommate and counselor, has found a job, and pays taxes. She has formed new friendships and has increased her independence, access to the community, and her self esteem. Although she has made great progress, she will continue to need long term services and supports for the foreseeable future.

o A twenty-five year old man in Maryland who is diagnosed as having paranoid schizophrenia has spent many months in psychiatric hospitals over the last several years. Although his disability and numerous hospitalizations had a serious impact on his ability to participate in school, he eventually earned his diploma. Through a community outpatient psychiatric rehabilitation program, he receives numerous long term support services which are enabling him to become more independent in the community. He receives assistance in keeping his medications under control, learning to use public transportation, learning job seeking skills and appropriate business attire and behavior, managing money and paying bills, and is learning to live on his own. He will need continued support in various aspects of his life in order to maintain and increase his ability to live independently and to avoid future hospitalization.

o A seventeen year old girl is experiencing major changes in her life as a result of traumatic brain injury during a car accident. She is having a slow recovery, is experiencing learning problems, frustration and extensive social changes, and attends school only half day while she receives rehabilitation services everyday. As she matures and as the extent of her injuries are revealed, she will need various supports over time, including services to assist her in making the transition from school to work and to assist her to become as independent as possible within her community.

o In Wisconsin, a young boy born with cerebral palsy and sensory impairments requires a tracheostomy tube to help him breathe, a gastrointestinal tube to help him eat, and other extensive medical, health, and social supports. He lives at home with his family, attends his neighborhood school, and relies on a number of basic supports from numerous sources such as the school system, private insurance, Medicaid waiver services, and state and county community and respite care services programs. While managing services from many different sources is complicated, the mix enables him to live at home and to stay out of an institution. He will continue to need support at school, specialized therapies, prescription medications, special diets, personal assistance, adaptations such as a lift on the family van, and support for community living as he grows older.

o A retired fifty-six year old woman with multiple sclerosis has periods when she is able to take care of herself with just a few hours of personal assistance a day. However, there are periods when her condition worsens and she is completely paralyzed, sometimes leading to hospitalization and the need for total care when she returns home. She needs a wide range of long term services that can be provided in varying intensities depending on her needs at a given time. However, her retirement income -- a small pension and some income from investments -- is insufficient to pay for these services. Medicaid does not provide the home and community based services she needs and, to be eligible for nursing home care when she needs total care, she would have to impoverish herself by spending all of her income-generating assets, at which point she would no longer be able to afford to live in her own home.

#### CCD APPROACH

CCD has considered the development of a comprehensive long term services program to be a critical need area for many years. A comprehensive long term services program would include supported living

services, personal assistance services, supported employment, assistive technology devices and services, and an array of community support services for people with disabilities.

CCD's Task Force on Long Term Services and Supports is a combination of two previous Task Forces. The Task Force on Long Term Services/Medicaid worked on issues related to the long term service provisions of Medicaid. The CCD Personal Assistance Services Task Force, created in 1990, included representatives from across the disability community, including people with physical, cognitive and other mental impairments, including mental illness, and sensory impairments. Together we worked to refine the draft bill Personal Assistance for Independent Living originally produced by the World Institute on Disability.

In addressing personal assistance issues, CCD established working groups on crucial issues of system design; training and compensation; quality assurance; eligibility & services; and due process. The deliberation of these groups lead to the development of a concept paper, Recommended Federal Policy Directions on Personal Assistance Services for Americans with Disabilities, that sets forth the philosophies and principles that CCD believes any comprehensive personal assistance services program must meet. This document is included as Appendix 1.

CCD has been meeting on an ongoing basis with the American Association of Retired Persons, the Long Term Care Campaign, the Older Women's League, the Alzheimer's Association, Families USA, and other groups representing elderly people to discuss and compare our long term service proposals with a view toward defining areas of consensus regarding long term services between the disability and aging communities. Ideas, views and opinions are exchanged among the groups through a number of meetings and forums. Together, CCD, AARP, and the Alzheimer's Association have presented consensus recommendations to the Administration Working Group on Long Term Care. While there has not been total agreement in all areas, there is enough common ground among the groups to establish an ongoing dialogue and a continuing working partnership.

## **REACTION TO PRESIDENT CLINTON'S PROPOSAL**

President Clinton's proposals on long term services (as embodied in H.R. 3600) have many strengths. He calls for a bold new commitment of \$38 billion per year (at full implementation) for services that are vitally need by people with significant disabilities. **If I am able to leave you with only one message today, it would be this: It is absolutely critical that long term services be part of the reform of our national health care system.** We must stress that ignoring long term services will short-change many people and limit the effectiveness of any health care reform.

There are many positive aspects to the President's plan and some areas where the plan can and must be strengthened. CCD is committed to work together with the Congress and the Administration to ensure that the best possible reform program be enacted. In addition to what is presented here, the CCD Long Term Services and Supports Task Force is preparing a paper addressing specific recommendations for statutory language and we will submit those additional comments to you within two weeks.

### **A. STRENGTHS OF THE PRESIDENT'S PROPOSALS**

There are many commendable components in the Clinton long term service proposal.

1. New Commitment to Long Term Services -- First and foremost is the President's willingness to commit new federal resources -- at least \$38 billion dollars per year at full implementation -- to expanding and improving long term services that are desperately needed by Americans with significant disabilities. This commitment will enable thousands of people with disabilities to access education and training programs, hold jobs, and participate in community activities -- often for the first time in their lives.

2. Emphasis on Home and Community Services -- CCD is pleased with the Clinton Administration's emphasis on expanding access to home and community based services rather than institutional services. In general, home and community based services are more cost effective than institutional services and afford people with disabilities greater opportunities to become contributing members of society. The overwhelming desire of most people with disabilities of all ages is to remain in their own homes and communities, while receiving the support services necessary to remain as independent as possible.

3. Eligibility Criteria -- The President's plan takes a positive step forward in attempting to cover people of all ages with all types of disabilities -- cognitive, mental, and physical. Historically, other proposals have excluded people on the basis of one type of disability, such as mental illness; CCD considers that approach unacceptable. The President's proposal also allows eligibility for all income levels, thereby beginning to address the marriage penalties of the income-based programs and the problem of people having to impoverish themselves in order to have the assistance they need to survive and prosper. It also addresses the work disincentives issue, where people who are receiving needed services accept a job, lose their benefits, and yet do not earn enough money to meet their basic living needs and purchase their disability-related goods and services.

4. Basic Philosophies -- The disability community is delighted to see that the Clinton proposal contains many principles and philosophies that we believe must be a part of any long term services system if it is to be effective. These principles include a commitment to consumer directed services, an option for the use of vouchers or direct cash payments, consumer involvement in planning the state long term services program, and individualized service needs assessments and plans of services.

These directions are particularly important because of the changing nature of the entire disability services system and we applaud the Administration's recognition of them. Services for individuals with disabilities historically have been delivered in a paternalistic manner. In light of the promise of empowerment implicit in the Americans with Disabilities Act, people with disabilities now expect to exercise an increasing degree of control over their lives, their rehabilitation and their support systems. Involvement in the design, direction, management, and assessment of their individual support services enables people with disabilities to exercise a degree of control over their own lives that is essential to physical and emotional well-being.

The ability of people with disabilities to participate actively at the planning level of long term services means that there will be a greater chance that the service system ultimately will meet the needs of those it is intended to serve. Given the number of jobs that will be created by a new \$38 billion a year program, this program represents a unique opportunity to employ some of the persons with disabilities in America (67 percent of whom are not working) through their participation in policymaking, administration, management, and direct service jobs that will be created.

5. Tax Treatment -- The proposed tax credits and changes in medical care deductions will help to offset the extraordinary expenses of living with a disability and assist people with disabilities to enter the workforce by giving them a measure of economic equity with those who do not need to pay these extraordinary costs.

6. A Good First Step -- CCD believes that the President's long term services plan represents a significant beginning for a system that should ultimately be comprehensive. While it is desirable to make long term services available right away to all individuals with disabilities who need them, CCD recognizes that fiscal restraints will necessitate the gradual phasing in of coverage in some orderly fashion. We are concerned about phasing in this coverage in an equitable manner so that people with varying types of disabilities and economic circumstances will be treated fairly and in a manner which ensures that their needs are appropriately met.

## **B. ISSUES TO BE ADDRESSED IN THE CLINTON PLAN**

In the previous section, I have described the numerous positive aspects of the President's proposal for long term services reform and, in particular, those areas which reflect the principles and philosophies which the disability community believes must be included in any true reform of long term services. In this section, I want to draw your attention to various issues that CCD has identified which raise serious concerns about the effect of the proposal on people with disabilities. We believe that these are not insurmountable obstacles and we look forward to working with the Subcommittee and the Administration to resolve these and other issues.

1. Eligibility Criteria -- The eligibility criteria contained in the proposal are too limited in several ways. Taken as a whole, the criteria would not cover many people who clearly need long term services. The President's principle of universal coverage would not apply to long term services where eligibility is so limited. Concerns regarding the specific criteria are as follows.



According to the Administration's own estimates, only about 25 percent of the people who need long term services and supports will be eligible to receive them under the proposed new, universal home and community funding authority. Congress should recognize that the use of the "3 out of 5 activities of daily living (ADLs)" test will leave many people with physical disabilities with substantial service needs without coverage.

The Administration-proposed equivalency criteria applicable to people with cognitive and mental impairments would similarly extend eligibility to only a small percent of people who need long term services. Successful community support programs have evolved which prevent or decrease utilization of institutional care by providing seamless access to services that include rehabilitation and assistance to people with cognitive or other mental impairments in areas such as: nutritional needs, including purchasing, storing, and preparing food; taking medications; and budgeting for food, clothing, and shelter. We want to ensure that people with serious cognitive or mental impairments who require such extensive ongoing services and supports are not excluded by the use of inappropriate criteria. The standard mental status exam proposed by the Administration has yet to be developed and validated. Responsibility for development of that criteria is left to the Secretary. While we recognize that the bill includes some significant changes (from prior drafts) regarding the need for supervision and in the use of instrumental activities of daily living, we want to assure that the process used to develop the standard criteria includes experts representing the broad range of types and causes of mental and cognitive impairments.

Finally, the criteria for use with children is far too limited. It would cover only children under age six who would otherwise require hospital or institutional care. This standard would, once again, use institutional need as the yardstick for eligibility, thereby furthering the institutional bias which already permeates the Medicaid program. The need for and availability of home and community services should not be benchmarked against institutional admissions criteria in the case of either children or adults. An earlier draft required that the child also be technology dependent. Such a requirement would be severely limiting and would likely leave children with equivalent disabilities who do not depend on respirators or other technological devices without the home based support that they need. Finally, it is not clear what happens to children over age six who otherwise meet the children's criteria and to children of any age who might qualify under one of the other criteria. Are criteria that are standardized on the adult population to be used in establishing the eligibility of children over six years of age?

CCD had submitted to the Administration proposed criteria which would attempt to reach people who do not meet the ADL and other tests yet have disabilities at levels equivalent to the 3 ADL criteria. Such criteria would give the Secretary flexibility in assessing other circumstances and factors for eligibility as needed. We believe that a provision granting the Secretary discretion regarding inclusion of other people on the basis of medical condition or other circumstances should be added. In addition, CCD's proposed criteria (Appendix 3) would have used the SSI functional approach (for evaluating disability only) for all children from birth to 18 years of age, that is: inability to function independently, appropriately, and/or effectively in an age-appropriate manner. We will propose specific recommendations regarding these eligibility issues in a separate paper within the next two weeks.

CCD believes it is important to note that, although the eligibility criteria are not ideal, the proposal reflects an understanding of the need to use different approaches for determining eligibility for people with differing disabilities. This is within the expressed intent of covering people with all types of disabilities, regardless of diagnosis.

2. **Scope of the Basic Service Package** -- There are two issues which must be addressed regarding services to be covered under the new home and community long term services program. One is the breadth of the service package and the other is the definition of personal assistance services itself.

a. **Breadth of the Basic Service Package** -- Regardless of the ultimate definition of personal assistance (discussed below), the proposed program must recognize that personal assistance services is only one element of the array of long term services and supports required by people with severe disabilities. As I stressed earlier in my testimony, severe disabling conditions occur in many forms and, thus, a broad array of services and supports must be available to appropriately address the needs of all eligible participants. There is a real danger that many eligible individuals -- especially people with significant mental and cognitive disabilities or multiple disabilities -- will be denied the full range and intensity of community services they need if this new federal funding authority is narrowly construed by the states. Given the fact that federal funding levels would be capped and the states granted broad discretion in determining the range of services to

be provided (i.e., other than personal assistance services), we believe that this danger is a real possibility which should be seriously addressed.

CCD believes that the services which are considered to be state options under the President's proposal should, in fact, be part of the basic service coverage in each state, in addition to personal assistance services. As stated in the proposal, these services include "any other community based long term care services including: case management, homemaker and chore assistance, home modifications, respite services, assistive technology, adult day services, habilitation and rehabilitation, supported employment and home health services not otherwise covered under Medicare, private insurance or through the basic health plan."

In addition, we believe that the bill language should be strengthened regarding the requirement for states to demonstrate in their state plans that the range of services to be offered will be sufficient to meet the needs of all eligible people regardless of the type of disability they have, their age, or the level of complexity posed by their disabling condition. In preventing the furtherance of the use of institutions, it is important that people have access to a full range of needed services and that they not be forced to accept institutional services for lack of adequate and appropriate home and community services. Costs should not be an issue in making these changes since the level of federal financial participation is capped. CCD's recommendations would, however, assure that people with disabilities will be eligible for similar services no matter where they live thus ensuring interstate "portability" of long term services and supports and that they will not be subject to the vagaries of state-level political decision making regarding vital services which they require through this joint federal/state program.

b. Definition of Personal Assistance Services -- In the Clinton plan, personal assistance services for the new home and community services program are defined by the state and must include at least "hands-on and stand-by assistance, supervision, and cueing with activities of daily living." CCD believes that the inclusion of supervision, standby assistance, and cueing is important and should remain in the definition.

However, CCD is concerned that the definition only references activities of daily living. This aspect of the definition will make the services useful primarily to people with physical impairments who meet the ADL test and will not address the personal assistance needs of people with mental or cognitive impairments who are otherwise eligible. CCD has recommended a broad definition of personal assistance services which would include the services needed by people with cognitive and other mental impairments and sensory impairments. This definition can be found in the paper Recommended Federal Policy Directions on Personal Assistance Services for Americans with Disabilities in Appendix 1.

Again, broadening the definition to include essentially any services which will assist the functioning of an individual should not affect the cost of the proposal since the home and community based services program is capped. Broadening the federal minimum definition will, however, allow the states to be more flexible in meeting the needs of all eligible people in the program. We note that the bill includes a much broader definition of personal assistance services in the (Section 7901) dealing with the tax credit. We will propose more specific recommendations.

The proposal makes a distinction between agency-administered and consumer-directed services. We note that, while consumer-directed or voucher programs may be the purest form of consumer control, even agency-run services can be designed to be consumer-directed in many respects.

3. Medicaid Long Term Services for People with Low Incomes -- Central to our analysis of the impact of the new program on people with disabilities is the elimination of the previously-proposed low income home and community services program. Instead, the bill assumes that the Medicaid program will continue to provide both home and community and institutional long term services to people who are eligible for Medicaid. Given the fact that the new eligibility criteria for the Administration's new long term services program is much more limited than the current eligibility criteria for Medicaid long term services, the continuation of community services through Medicaid is absolutely essential to meet the needs of people who are now eligible for Medicaid as well as people who may become eligible for Medicaid in the future. For example, under the Medicaid optional programs now available to people with serious mental illnesses (targeted case management, clinic services, and rehabilitation services), innovative long term services have reduced unnecessary or prolonged institutional care, homelessness (which can be prevented or ameliorated with assertive community treatments when not restricted by arbitrary limitations) and inappropriate incarceration of children and adults when there are no other places of treatment or supports because of inadequate funding in the health care system.

CCD believes that it is necessary to continue to make improvements to the Medicaid long term services programs so that they will better reflect state of the art approaches in serving people with disabilities. Such improvements are needed in: the home and community based waiver program (including the expansion of the definition of habilitation services to include supported employment for all waiver recipients), making the community supported living arrangements services program a coverage option under all state Medicaid plans, eliminating the discriminatory treatment of low income people with mental illness under the Section 1929 home and community-based state plan coverage option, the Intermediate Care Facilities for the Mentally Retarded (ICF/MR) option, and improving administration and regulation of OBRA 1990 PASARR requirements regarding inappropriate nursing facility admissions. CCD has previously submitted to Congress specific proposals for dealing with each of these limitations in current Medicaid policy; and, I would stress, none of them have been shown to cause a significant increase in federal-state Medicaid spending.

It should also be noted that most current Medicaid long term services are optional to the states. In conjunction with the differential federal match available to states for services under the new home and community program (expected to be significantly higher than the match for the remaining Medicaid program), there is significant fear that states will divert existing Medicaid matching dollars that currently are being used to furnish community services to low income people who need them but who would be ineligible under the new program's stricter eligibility criteria. This potential situation raises serious issues of long term security for individuals and their families and must be addressed in any forthcoming legislation.

We will be submitting more specific recommendations regarding these Medicaid issues within two weeks.

4. Consumer Involvement -- As discussed above, the Administration proposal rightly includes a new focus on consumer involvement in various aspects of federal and state policymaking. CCD believes that this positive direction should be enhanced with greater attention to consumer involvement in state planning and program design, and in quality assessment of the services and supports and the system through which they are provided. CCD submitted extensive consumer participation recommendations to the Administration earlier this year. These recommendations, which would enhance the role of consumers and their representatives at the policy and implementation levels, are attached as Appendix 4.

In addition, it is crucial that the proposed Medicaid Commission (to be appointed to determine the future of Medicaid acute and long term services) have adequate representation and input from all areas of the disability community. As major consumers of Medicaid acute and long term services, the disability community must be heard and must be a full participant in efforts to develop the Commission's recommendations. We believe that the Commission must have full staff support and must have the resources to support the disability-related costs of participation of Commission members with disabilities. We will submit further recommendations regarding this issue.

5. Institutional Bias -- The current Medicaid program contains clearly recognized institutional biases which CCD believes should be eliminated and thus should not be carried forward into or exacerbated by any new home and community services funding authorities. According to unpublished data prepared by Systemetrics, Inc. for HCFA, approximately 85% of the \$38.9 billion in Medicaid expenditures for long term services for low-income people in FY 1992 was spent for care in institutional settings (nursing facilities and ICFs/MR) while 15% was used for home and community-based services. It is our hope that the creation of a new community long term services program would help to reverse these current biases. However, there are some features of the proposal which we believe threaten to establish new biases in favor of institutions. They include: establishing a cap on expenditures for the new community services program while the nursing facilities and ICFs/MR remain uncapped; new mandates for medically needy spend-down programs for institutional services but not for community based services; proposed increases in the resource limits and personal needs allowance, which are sorely needed but which are targeted only to people living in institutions without comparable income and resource protections for people living in the community; and the lack of a limit on out-of-pocket expenses for long term services (see further discussion below regarding co-payments). [The Administration's subsequently-abandoned low income proposal contained features which many believe would have further exacerbated the institutional biases of the Medicaid program. We believe that those features were completely unacceptable, but will not dwell on them here.] We urge Congress to address these institutional biases and we will submit more specific recommendations.

6. Equity in Co-Payments -- As in the acute portion of the plan, CCD believes that more work is needed on the co-payment sliding scale. The amount an individual or family (with a member living at home) is required to pay should also be capped, based on a percentage of income. Otherwise, the current co-payment structure may make home and community long term services exorbitantly expensive for people with low incomes. Particularly since people with higher incomes will be eligible for services, it is imperative that the costs of services not be out of reach of low and middle income individuals and families. This would be especially true of individuals with high service needs and costs. Is it fair that a family of four with a net taxable income of \$24,000/year which is supporting a ventilator-dependent child at home, whose costs total \$85,000, should pay fully 10 percent of the cost with no cap, while they would incur no costs if the child were institutionalized in a Medicaid certified long term care facility? Similarly, should not a couple with net income of \$125,000/year and community services costs of \$8,000 be required to pay more than \$3,200 per year?

Further, it is unclear what impact the tax credit will have on low and high income people in relation to their co-payment costs. We are concerned that the tax credit does not appear to be available for working families with children with disabilities and families with non-working adult members with disabilities and the tax credit has been written to apply only to people with physical disabilities. In addition, there is great concern within the disability community with the proposed prohibition against allowing states to use income as a basis for allocating resources during the phase-in, since this will prevent states from targeting resources to those most in need.

7. Children -- Special attention must be paid to the effects of the proposal on children. Children who lose Medicaid coverage because they are covered by the alliance health plans should not lose their access to important therapy and other long term services and the protections of the Medicaid Early and Periodic, Screening, Diagnosis, and Treatment program (EPSDT). Forcing these children to go without cost-effective extended services would be unacceptable. The failure to fully cover these vital services also would jeopardize early intervention and education-related services under Part H and Part B of the Individuals with Disabilities Education Act by withdrawing a major funding source at a key time during implementation. This would be especially important for infants, toddlers and children who do not meet the eligibility test for the new program. We are still analyzing the bill's approach to coverage of these essential services and will make more specific recommendations in the near future.

8. Payment Rates -- Payment rates for providers must be high enough to enable them to cover legally required employee benefit payments such as Social Security, Medicare, tax withholding, and the new employer-mandated health insurance premiums. This is particularly an issue in voucher and cash payment situations where the individual with a disability directly hires his/her personal assistants. Experience in several states has shown that people either have to go without essential services or they get the services by paying below legally required minimum wages and benefits. We are reviewing other issues related to providers in the bill.

9. Private Long-Term Care Insurance -- While we do not believe that private insurance will be able to adequately meet the long-term service needs of persons with disabilities of all ages, we recognize that it may help to pay some of the long-term service costs of those persons with disabilities (generally older people) who are able to afford and maintain private coverage. Since numerous inadequacies and abuses in the long-term care insurance market have been well documented, we believe that private long-term care insurance should not be given preferential tax treatment unless adequate standards are in place to protect consumers from such practices. It is imperative that the inequities that we are attempting to correct in the acute care insurance market not be permitted to continue in the long-term care insurance market.

We are pleased that the Administration's proposed standards address many of the current inadequacies and abuses and, most importantly, include a prohibition on discrimination in the provision of benefits based on a person's diagnosis. Currently, insurers routinely deny benefits if a person's functional impairment or disability is due to a "mental" condition. In fact, the National Association of Insurance Commissioners (NAIC) Model Regulations state that such limitations are acceptable. Therefore, it is essential that the Administration's proposed standards not be weakened in any way.

We would further strengthen these regulations by referencing the obligation of insurers to comply with the Americans with Disabilities Act (ADA) when medically underwriting long-term care insurance. Currently, insurers routinely deny long-term care insurance coverage to persons with preexisting conditions, whether or not the condition is related to a need for long term services. The ADA requires that underwriting



and the classification of risks be based on sound actuarial principles, or be related to actual or reasonably anticipated experience. The Department of Justice preamble to the final regulations for Title III of the ADA states clearly that individuals with a pre-existing condition cannot be denied coverage for an illness unrelated to the pre-existing condition. Because existing NAIC standards and state regulations do not in any way prohibit this discriminatory practice, it is essential that federal standards reference the obligations of insurers under the Americans with Disabilities Act.

10. Other Issues -- There are numerous other critical issues which will need to be addressed in ensuring that the proposal can meet the needs of people with disabilities. These include: the need to provide psychiatric services required over time which are beyond those covered by the basic benefits package; the need to resolve issues regarding state medical practice and nurse practice acts in relation to health-related tasks performed by personal assistance providers such as medication administration and catheterization; the relationship between acute health services and long term services for people with disabilities including clarification of treatment of services such as "outpatient" rehabilitation services which might be considered acute or long term services; an assessment of the impact of the state option for making capitated payments to health plans or other providers for community based long term services; and the length of time until full implementation of the long term services proposal. The relationship between acute health and long term services is problematic for all people with serious and persistent physical, cognitive, and mental disabilities; for people with psychiatric disabilities, there is the additional question of the linkage to essential long term services for people who exceed limitations for non-residential intensive services until the year 2001 when full coverage is scheduled to be in effect. The Task Force will propose more specific recommendations in the forthcoming paper.

Again, CCD looks forward to working with this and other Committees of Congress to address the President's long term services proposal. We believe that long term services are a critical component of health reform and that the President has made a significant and important commitment and step forward with the proposal of a new home and community long term services program to serve people with disabilities of all ages without requiring impoverishment for eligibility. We urge Congressional support of this commitment and for inclusion of a strong long term services component in legislation to restructure the American health care system. We pledge to work with you to ensure the availability, appropriateness and effectiveness of such supports for all people with disabilities.

Mr. BROWN. Ms. Canja.

### STATEMENT OF TESS CANJA

Ms. CANJA. Thank you, Mr. Chairman. I am Tess Canja, a member of the AARP's Board of Directors.

Most of us have had personal experience or friends or family who have had to cope with the financial, physical and emotional stress of meeting long-term care needs. For you as policy-makers, it is natural to translate long-term care into a vision of Federal budget dollar signs. Families involved in long-term care also see dollar signs. They see huge dollar signs as they struggle to pay for home care for a child or spouse or parent while still dealing with college tuition costs and a home mortgage.

Caregivers, most often daughters, spouses and mothers, see not only the direct cost of giving care, but also the income lost, both now and in the future. Caregivers often forego higher paying job opportunities. They work part-time or they give up their jobs altogether. Each of these decisions means less income now, less pension, and less social security income in the future. The government also pays in lost tax revenue and higher assistance costs later.

Health care coverage for acute illness alone will not give families real security and peace of mind. For families, there is no difference between spending \$20,000 on home care or \$20,000 on hospital care. It is still \$20,000 that they don't have. The President's proposal for a new home- and community-based care program recognizes that few families can afford the cost of long-term care. It also recognizes that the need for long-term care extends to all ages.

In our own family, I have a grand niece who was born with spina bifida. I have a cousin who at the age of 21, after working late at night fell asleep at the wheel and has been a quadriplegic ever since. I have an 86-year-old mother for whom I have a caregiver and she is disabled and needs assisted living.

AARP appreciates that the President's proposal focuses eligibility on measures of disability, not age and not income. We also appreciate that we give persons of all generations new choices and address the current system's institutional bias by helping families avoid having to place their loved ones in a nursing home.

The President's home- and community-based care proposal also would be good for our economy by creating approximately one million new jobs—we have a new study that shows that—by providing assistance to working caregivers and by helping some adult disabled persons become productive taxpaying members of society.

There are a number of areas, however, in which we believe the proposal could be strengthened. For example, stronger incentives should be created to encourage States to participate in the program.

Another, while we agree that there is merit in State administration of a home- and community-based program, provisions should be included to improve State accountability and to ensure that tax dollars are appropriately spent.

In addition, the liability of the funding within the proposal's caps should be improved to provide—reflect certain limited cost increases that are beyond the control of the States.

Although we are pleased to see even the small improvements in Medicaid nursing home coverage, millions of persons would remain vulnerable to bankruptcy due to expensive nursing home costs. Studies show that people's greater fear is impoverishment from nursing home costs, which now average \$30,000 a year, and can go as high as \$60,000.

It is also important to clarify that the President's long-term care proposal is not a new entitlement program, but it is still a vast improvement over our current nonsystem. The President has made an important far-reaching start toward achieving security against the overwhelming human cost of long-term care. Since it does not, however, meet the full extent of the need for long-term care, we must be careful not to over sell it.

The President's statement in his State of the Union address that the American public is way ahead of politicians on the issue of health care reform is instructive. We believe this is particularly true with long-term care. The findings from each of four surveys that an independent firm conducted for AARP between April of 1993 and this January all show that public support for health care reform increases dramatically when long-term care is included.

In conclusion, Mr. Chairman, AARP commends the President and members on both sides of the aisle who have brought the debate to this stage. As we go forward, we ask you to consider the cost to American families of not including long-term care in health care reform. The President's home- and community-based care proposal can begin to provide greater security and protection now and a solid foundation for the future.

Thank you.

Mr. BROWN. Thank you, Ms. Canja.

[Testimony resumes on p. 339.]

[The prepared statement of Ms. Canja and an AARP statement follow:]

STATEMENT  
of the  
AMERICAN ASSOCIATION OF RETIRED PERSONS

Good Morning. My name is Tess Canja and I am a member of the Board of Directors of the American Association of Retired Persons (AARP). Thank you for the opportunity to testify today as the Subcommittee reviews one of the most critical problems facing families today: the need for long-term care.

Over the past several years we have listened closely to what the American people, including our diverse membership tell us they want in a health care system. Despite their differing circumstances, the vast majority of Americans, old and young, have consistently stressed the need for broader protections against the high costs of health and long-term care. How is it, they ask, that we cover the cost of a lengthy hospitalization, in the tens of thousands of dollars, but we do not help with the cost of nursing home or home care? Some assume that concern about and support for long-term care coverage is confined primarily to the older population, but, in fact, strong support exists across all age groups. The 50-64 age group is particularly concerned, both for their parents and themselves. It is this middle generation, particularly the women, who see and feel the staggering costs -- financial and emotional -- of long-term care. It is they who bear the costs of providing care in the home and then the costs of institutional care when it can no longer be avoided.

AARP commends President Clinton for his bold and constructive plan for accomplishing reform. We also commend the First Lady, Congressional leaders in both parties, and this Committee for a commitment to addressing this issue now. The nation has waited too long for comprehensive reform. We must use this unique point in history to enact true reform



which covers everyone, maintains high quality care, makes health care costs affordable, and includes coverage of both prescription drugs and long-term care.

**The inclusion of long-term care in the health care reform legislation is vital to our members and their families and is critical to AARP's support for any health care reform proposal.** Historically, many Americans have equated long-term care with nursing home care. Long-term care, however, is much more than just nursing home care. It includes a wide range of home and community-based care as well as residential alternatives.

**AARP is very pleased that the President's proposal includes coverage for home and community-based care for persons of all ages and incomes.** The President's proposal represents a serious start towards addressing the unmet long-term care needs of millions of American families.

Too many reform proposals focus only on acute care and simply ignore the long-term care needs of American families, as if these needs were so easily compartmentalized in the lives of these families. These proposals are fundamentally flawed because they fail to address the need for a full continuum of care throughout an individual's life. Without long-term care coverage, no family has real security against the crippling costs of serious illness or disability.

Long-term care is typically considered a benefit for the elderly. This is a myth. The need for long-term care crosses generational lines. An estimated 10 million persons need some form of long-term care. Approximately one-third of these individuals are under age 65. Many are children. Moreover, the need for long-term care is felt not just by those requiring care, but also by their families -- often those providing and paying for care. This is particularly true in the case of those in the "sandwich generation," caught between meeting the needs of their children and their parents.

### **Health Care Reform Must Include Long-Term Care**

While approximately 38 million people lack basic medical insurance, virtually all Americans lack protection against long-term care expenses. With average annual nursing home costs of over \$30,000 (and some areas experiencing costs of \$60,000 or more) and home health care costing from \$50 to \$200 per day, long-term care out-of-pocket costs can often devastate a family. For most people, the cost of long-term care is an unmanageable financial burden. Many families are also shocked to find -- only too late -- that neither Medicare nor private insurance covers long-term care to any great extent. To a family sitting around the kitchen table, there is no difference between spending \$20,000 on hospital care and spending \$20,000 on home care. It is still \$20,000 they do not have. Therefore, to achieve true security, savings, and quality in our health care system, care must not be limited to the provision of services by a hospital or doctor; long-term care must also be included.

The need for comprehensive services -- It makes little sense to provide financial protection against the cost of an acute illness but leave people vulnerable if they suffer from a chronic and disabling condition, especially since the need for these services often is so interrelated. Results from research conducted on the Social Health Maintenance Organization (SHMO) demonstrations in the late 1980's illustrates why integrated care is so important -- custodial and skilled services are often needed to complement one another. Almost 70 percent of initial referrals for community-based long-term care originated from hospitals and other parts of the medical care system. Moreover, 37 percent of the care plans developed for home and community care included concurrent authorization for medically necessary skilled services. In addition, individuals' levels of disability frequently changed and was tied to acute episodes of illness. Without comprehensive benefits, effective patient care will not be achievable, and costs "avoided" in long-term care may instead show up as costs in the acute care setting.

Caregivers are being unfairly burdened -- Family members provide the vast majority of long-term care to persons of all ages. But caregivers place their own health in jeopardy and frequently are forced to leave the labor market, thereby suffering not only short-term loss of income, but also long-term reduction in Social Security and private pension benefits.

In a recent focus group, a woman in her 50's related her story:

Rose had held a good job with a large corporation until her mother needed long-term care. Unable and unwilling to place her mother in a nursing home, Rose quit her job -- 6 months before her pension would have vested -- to care for her mother.

She saw her future income potential and retirement security disappear as she made the painful decision to take care of her mother -- for the next seven years.

There are many stories just like this. They typically involve women in their 50's -- primarily spouses and daughters -- who sacrifice financially, physically, and emotionally to assure that a loved one is cared for. Institutionalization of loved ones often occurs because of caregiver "burnout" if no outside help is available. The Association believes that caregivers deserve strong support.

Private sector solutions cannot work -- The private market has not provided nor can it provide adequate and affordable protection against the cost of long-term care. Private long-term care insurance that provides meaningful coverage is very expensive and generally excludes people with pre-existing conditions or mental disorders. Few people can afford the cost of private long-term care insurance for any length of time, particularly if the policy provides meaningful protection. Private long-term care insurance policies have done a particularly poor job in trying to cover home care because insurance companies are not confident of their ability to control the risks and demand involved.

#### **Public Support for Long-Term Care**

Americans of all ages strongly support health care reform that includes coverage for long-term care. A random sample survey of 2,020 adults conducted for AARP by the ICR Survey Research Group this past April found that 90 percent of the respondents felt that including long-term care in a health reform proposal was important. Support for health care reform



increased from 46 percent to 82 percent when long-term care was included (see Attachments 1 and 2).

According to a survey conducted in the fall of 1991 by DYG, Inc., three-fourths of Americans (18 and older) were "very concerned" about paying for the cost of long-term care. The concern, which is felt sharply by both men and women, extends to all income and age groups. In fact, concern about long-term care was greatest among persons age 50-64 -- those most likely to be caring for older parents and worrying about their own futures (see Attachments 3-7).

In a Harris survey conducted during December 1992 and January 1993, 91 percent of the respondents said they could not afford long-term care when they were told it would cost \$15,000 to \$60,000 a year, or \$40 to \$160 a day. With regard to a federal program providing long-term care in the home for the chronically ill or disabled, over 80 percent of these same respondents favored such a program not only for people 65 years of age and older, but for younger adults and children as well.

### **AARP Views on Long-Term Care**

To make long-term care coverage affordable and accessible to all Americans, the Association believes that the ideal solution is a social insurance program, similar to Medicare and Social Security, that would provide a comprehensive set of benefits in the home and community, as

well as in nursing homes. A social insurance program would require financial contributions from all members of society and would provide protection to all who need long-term care, regardless of age or income. Such an approach would spread the risks so that the costs to any one person would be small, while offering protection and appropriate care to all. Under such a social insurance system, private sector initiatives would supplement the public system by covering coinsurance, deductibles, and additional needed services.

Other fundamental principles that underlie AARP's views on long-term care include:

(1) provision of a comprehensive range of services, including institutional and home and community-based care; (2) effective cost containment mechanisms; (3) financing which is equitable, broadly based, and affordable to all individuals; (4) coordination between the acute and long-term care systems to assure a continuum of care across an individual's lifetime; (5) assurance of high quality care; and (6) support for informal caregivers.

These principles are at the foundation of AARP's proposal for comprehensive health care reform -- "Health Care America." The proposal, which was developed with the extensive involvement of AARP members across the country, would create a new Medicare-like program to provide comprehensive coverage for both acute and long-term care. The nursing home component of the proposal would be available over the entire length of an individual's stay, excluding coverage for room and board.

**The President's Proposal for Home and Community-Based Care**

The Health Security Act includes a significant, much-needed proposal to provide home and community-based care to millions of American families. The proposal represents a dramatic improvement over our current "non-system."

The President is on the right track in basing eligibility for the new home and community-based program on levels of disability, rather than age or income. Given the limited resources available, it is appropriate that the program target the most severely disabled individuals. An eligibility assessment and determination based on level of disability, when combined with the proposed care plan, would begin to address the serious problems of fragmentation and unmet need that currently exist for disabled persons of all ages. Age is not a viable eligibility criterion because approximately one-third of persons with severe disabilities who need home and community-based care are under age 65. In addition, while the program does ask persons with greater income to pay more for their long-term care services, it is not based on a welfare model. Therefore, those in need would not be forced to bankrupt themselves before getting help, as they must do now, to be eligible for Medicaid.

The President's proposal for home and community-based care would provide much needed support to caregivers who are shouldering enormous burdens by taking care of their loved ones and often missing work to do so. Many caregivers perform these services out of a

strong family commitment and a desire to postpone nursing home placement for as long as possible.

The President's proposal also would begin to provide to disabled persons and their families real choices about how to arrange for and where to receive the most appropriate care.

Today, people are forced into nursing homes prematurely or going without care because they do not have access to affordable home and community-based care. Historical patterns in public spending reflect a perverse bias, where approximately four out of five dollars spent on long-term care go to institutional care. This creates situations in which families are broken apart and Americans are denied care in the most appropriate setting, as well as where they would like to receive it. For the first time, under the President's proposal, many disabled Americans could receive services through the full continuum of care.

The Health Security Act proposal also includes reasonable cost-sharing and low-income protections which will discourage overutilization and yet help ensure that care is affordable for those who need it.

The President's home and community-based care proposal will also have a positive impact on the economy. For example, Lewin-VHI has estimated that the proposal would ultimately create approximately one million new jobs. Working caregivers would be better able to stay in their jobs and absenteeism would decline, thereby improving productivity. Many adult



adult disabled persons would, for the first time, be able to work and become productive, taxpaying members of society with the proposed assistance available to them.

### **Suggestions to Strengthen the President's Home and Community-Based Care Proposal**

The Association strongly applauds the President for recognizing the need to expand coverage and options for home and community-based care.

We agree with the need to contain long-term care costs and to keep federal expenditures under control, given limited resources. Effective care management and appropriate provider reimbursement should help in this regard. However, certain elements of the proposal that are designed to limit program costs and others relating to the role of the states raise particular concerns. In this regard, the Association has a number of specific suggestions for strengthening the proposal.

### **Proposals to Limit Program Costs**

Caps on Funding -- The proposal is, in effect, a matching grant program to the states. We have questions about how this would work. The capped nature of the proposed program makes it all the more critical that the data and criteria used to estimate full funding over time are accurate. Otherwise, funding shortfalls could easily occur, resulting in potentially serious levels of unmet need. What would happen if the program ran out of money before

the end of the fiscal year? Could services to persons currently receiving care simply be cut off? To help prevent this from occurring, baseline estimates must include accurate cost and utilization assumptions for all groups of eligible persons, including severely disabled children. In addition, could individuals lose eligibility at the end of each year's grant?

The adequacy of inflation and trending factors are a concern because they do not seem to account sufficiently for future changes in the intensity of service needs or real wage growth among workers in the very labor intensive home care area.

To help address these concerns, we recommend that the caps on funding for home and community-based care be accompanied by the same safeguards as caps on low-income subsidies for acute health care services. Specifically, an additional 15 percent cushion should be included as a margin of error, and any excess funds should be permitted to be carried forward and not be charged toward the next year's cap.

Definition of Disability -- The Association is pleased that the proposal would cover persons who need stand-by assistance or cueing to perform 3 or more ADLs. However, we would ultimately like to see a 2 of 5 ADL standard.

## Issues Regarding the Role of the States

Option for the States -- Under the proposal, states would have the option of not participating in the program. This could pose serious problems for consumers. Some states may elect not to establish a program or may postpone participation until much later in the phase-in schedule. Consideration should be given to strengthening incentives for state participation.

State Accountability -- While we agree with the Administration that there is merit in state administration of the home and community-based program, the Association believes that, to ensure accountability, state flexibility must be balanced by a clear federal framework for state participation and strong, effective federal oversight. Standards should ensure that federal dollars are being spent appropriately, that consumers are protected, and that a range of services are available. Federal oversight should include review of state plans and monitoring of compliance with standards. Careful reporting of substandard performance should be accompanied by strong enforcement tools. Particular attention should be paid to monitoring states so that they do not simply shift eligible Medicaid recipients into the program during the phase-in period, without extending services to other vulnerable persons.

State Incentives for Residential Care Alternatives -- One way to promote savings through competitive market forces would be to provide strong incentives to assist the development of residential alternatives to nursing home care, such as assisted living. Experience in Oregon, for example, has shown assisted living to be a cost effective, preferred alternative to nursing

home care for many frail elderly. Although we are pleased that the proposed home and community-based care benefit would be portable and available to eligible persons in these settings, more needs to be done on the capital and housing side of the equation. Ways to make such residential options affordable to persons with low and moderate incomes should be specifically addressed.

### **Nursing Home Care and Medicaid Improvements**

In addition to a new program for home and community-based care, the President's proposal also would include modest improvements for those who need nursing home care.

Specifically, it would: (1) require all states to have medically needy programs under Medicaid; (2) give states the option to increase the level of protected assets for single persons from \$2,000 to \$12,000 for purposes of Medicaid eligibility; (3) increase the minimum Medicaid personal needs allowance from \$30 to \$50 (scaled back from \$100 in the September 1993 draft); and (4) create new uniform federal minimum standards for private long-term care insurance policies, together with certain tax clarifications.

Although AARP is supportive of these modest attempts to improve Medicaid, millions of Americans would remain vulnerable to impoverishment due to lack of protection against enormous nursing home costs. The cost of a nursing home stay now averages \$30,000 a year and can exceed \$60,000 in some parts of the country. Studies conducted for AARP in 1989 and 1991 by DYG, Inc. found that while people prefer home care, it is the cost of



nursing home care which individuals fear most when they consider their long-term care needs, and it is this concern that appears most related to their willingness to pay increased taxes to finance new benefits.

Long-term care insurance standards -- AARP strongly supports the requirement for uniform federal standards for private long-term care insurance. Such reform is long overdue. Findings from studies conducted by the U.S. General Accounting Office, the Office of the Inspector General, and by Project Hope for AARP clearly demonstrate that the current state regulatory system has failed to provide sufficient consumer protection throughout the nation. We do, however, have some questions about the costs and distributional effects of the tax clarifications proposed in this area, particularly for those selling insurance policies.

AARP agrees with many of the proposed standards in the President's proposal. We are particularly pleased by the Administration's approach on two key issues: inflation and nonforfeiture protection. In our view, inflation protection should be offered to all prospective buyers and nonforfeiture protection should be mandatory for all long-term care insurance policies. These views are consistent with the current standards proposed by the National Association of Insurance Commissioners (NAIC).

Incremental Nursing Home Reforms -- If sufficient funding for a comprehensive nursing home program is not available at this time, less expensive incremental reforms could help many people. For example, one option would be to reduce the inappropriately high \$87

Medicare Skilled Nursing Facility daily coinsurance and make it more consistent with the extended care benefit available in the President's proposed basic benefit package through the alliances. We also strongly urge that the proposed optional increase in the level of assets protected under Medicaid for single persons (from \$2,000 to \$12,000) be made mandatory, as was originally proposed in the September 1993 draft, since states are very unlikely to provide such protection voluntarily. Further, in our view, the amount should be increased beyond \$12,000 so that people need not spend-down to such a low level before receiving protection.

The President's proposal should also do more to promote the key principles of savings and choice for Americans who need nursing home care. Nursing home costs must be contained and the access problems that low and middle income applicants experience in gaining admission to the nursing home of their choice must be addressed. Hospitals and other providers will have incentives to shift costs to this sector if it is the only one not subject to some form of spending limits. These goals could be furthered by making charge data available to consumers and prohibiting discrimination in admissions on the basis of wealth and source of payment.

### Conclusion

On June 8, 1988, the late Senator Claude Pepper brought a bill covering home and community-based care to a vote on the House floor. Much was said by many members about

the need to provide this kind of protection. Even opponents, who argued that the timing was not right, spoke eloquently about the importance of covering services in the home. Just before the proposal was defeated by a 169-243 vote, Congressman Pepper stated:

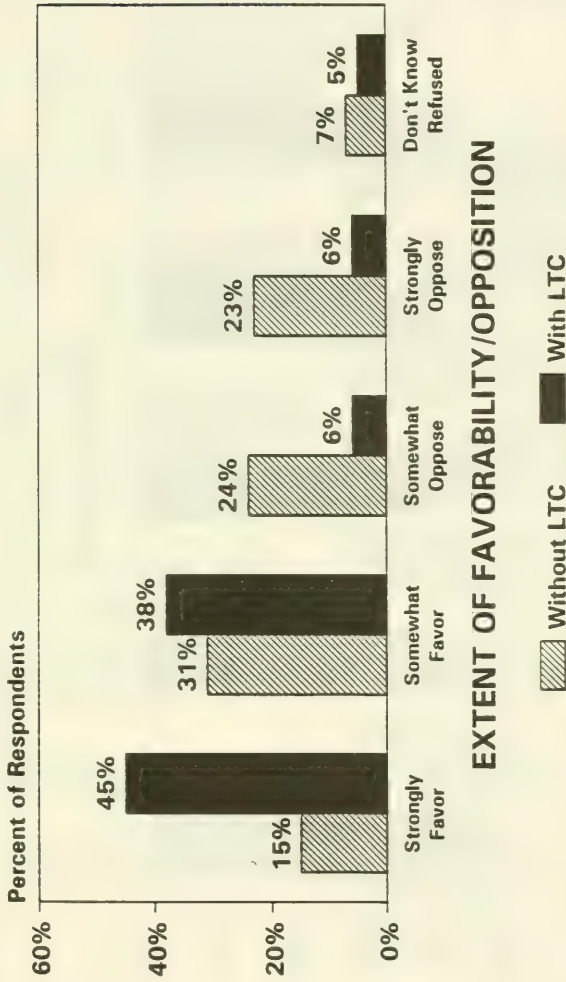
This is a day for which I have waited and worked, and I might say prayed for, for 50 years -- a chance to lighten the burden upon the masses of the people of this country, trying to help those saddled with a long-term illness....We can help millions of people to meet crises in their homes that are heart-rending in their character. When are we going to have another opportunity if we lose this one?

The opportunity has now come. We have a chance to begin to create a new system that removes the existing bias in favor of placing people in institutions for the rest of their lives; a system that does not force people to bankrupt themselves and go on welfare in order to receive help; a system that does not force caregivers to quit their jobs or jeopardize their own health to continue caring for loved ones; and a system that is not as intimidating for those who need to use it.

As advocates and policymakers we will need to educate the public that long-term care is a family issue, affecting disabled persons of all ages. The public should also understand the specific benefits of and limits to the President's proposal. The limitations of this program will loom larger in the public's eye in the future if they come to believe that there is more coverage and protection in the program than really exists. But the fact that it does not provide all the answers for everyone in need, cannot be an excuse for doing nothing. The President's proposal is a very important, significant start and a vast improvement over our current long-term care "non-system." Our job is to shape and improve the proposal so that it will provide real protection now and a solid foundation for the future.

AARP looks forward to working with members of this Subcommittee to help realize these goals and ensure that long-term care remains an integral part of whatever health care reform package is enacted.

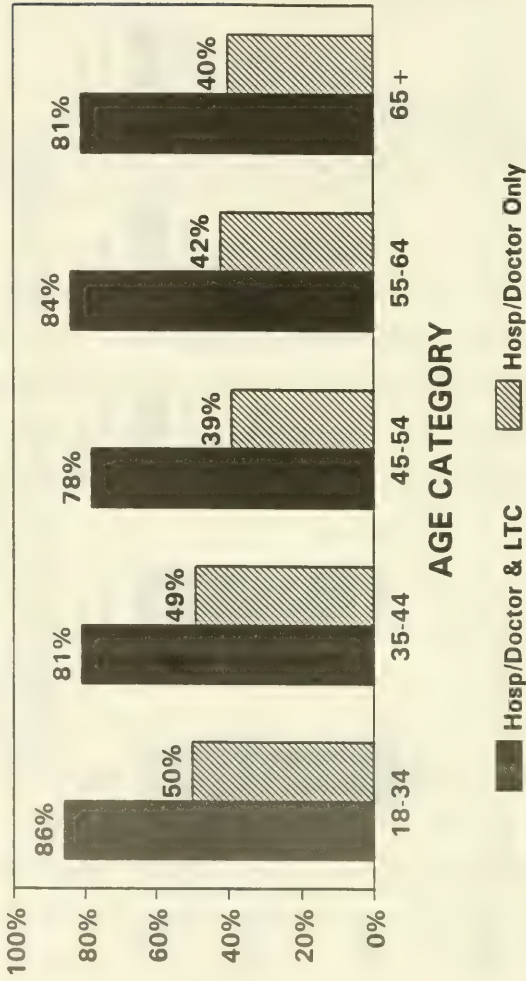
# **FAVOR/OPOSE HEALTH CARE REFORM PLAN WITH AND WITHOUT LONG-TERM CARE COVERAGE**



AUS/ICR Survey Research Group  
Excel Omnibus Study  
April 21-27, 1993 (N = 2,020)



**PERCENT FAVORING HEALTH REFORM PLANS  
WITH & WITHOUT LONG TERM CARE COVERAGE  
(BY AGE CATEGORY)**

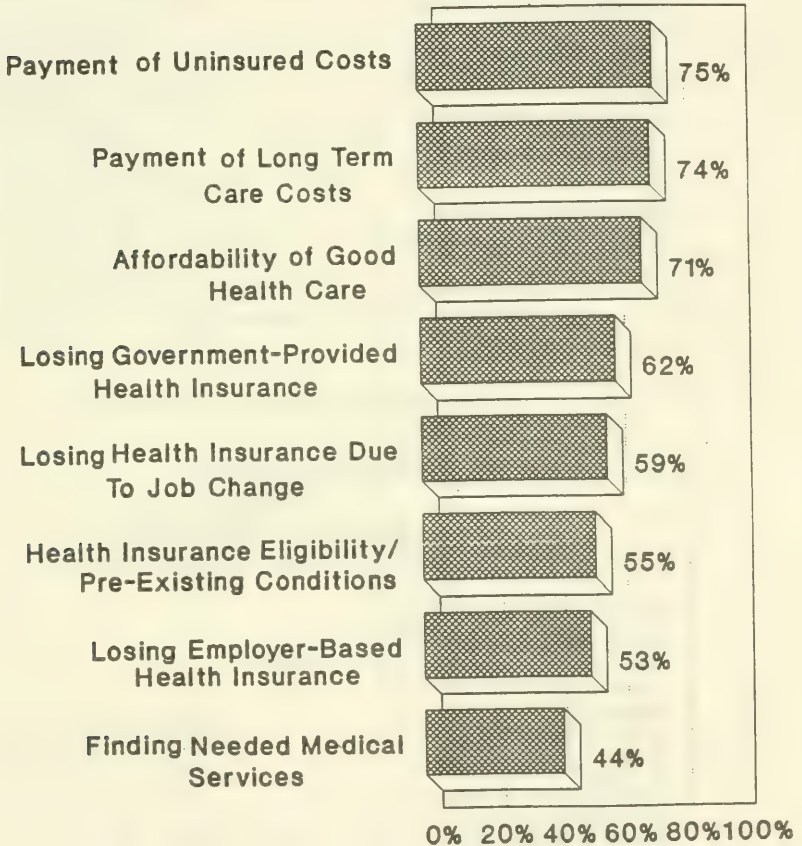


AUS/ICR Survey Research Group  
Excel Omnibus Study  
April 21-27, 1993 (N = 2,020)

# Ratings of Health Care Concerns

## Total Sample

Very Concerned About:



## ATTACHMENT 4

Ratings of Health Care Concerns

	<u>Total</u> %	<u>Total</u> <u>Women</u> %	<u>Total</u> <u>Men</u> %
<u>Very Concerned</u> <sup>1/</sup>			
Being able to pay for costs of health care not covered by insurance/government	75	75	75
Being able to pay for the cost of long term care such as nursing home care	74	76	73
Being able to afford good health insurance	71	70	71

Continued...

<sup>1/</sup> Rating of "4" on a 4-point scale

## ATTACHMENT 5

Ratings of Health Care Concerns

	<u>Total</u> <u>Women</u> %	<u>Women: Age</u>		
		<u>18-49</u> %	<u>50-64</u> %	<u>65+</u> %
<u>Very Concerned</u> <sup>1/</sup>				
Being able to pay for costs of health care not covered by insurance/government	75	74	82	70
Being able to pay for the cost of long term care such as nursing home care	76	72	85	78
Being able to afford good health insurance	70	69	85	60

Continued...

<sup>1/</sup> Rating of "4" on a 4-point scale

## ATTACHMENT 6

Ratings of Health Care Concerns

	<u>Total Men</u>	<u>Men: Age</u>		
		<u>18-49</u>	<u>50-64</u>	<u>65+</u>
	%	%	%	%
<u>Very Concerned</u> <sup>1/</sup>				
Being able to pay for costs of health care not covered by insurance/ government	75	75	76	76
Being able to pay for the cost of long term care such as nursing home care	73	69	80	79
Being able to afford good health insurance	71	73	75	58

Continued...

<sup>1/</sup> Rating of "4" on a 4-point scale

## ATTACHMENT 7

Ratings of Health Care Concerns

	<u>Total</u>	<u>Income (\$Thousands)</u>		
		<u>Under 25</u>	<u>25- 49.9</u>	<u>50+</u>
	%	%	%	%
<u>Very Concerned</u> <sup>1/</sup>				
Being able to pay for costs of health care not covered by insurance/ government	75	80	78	59
Being able to pay for the cost of long term care such as nursing home care	74	77	74	68

Continued...

<sup>1/</sup> Rating of "4" on a 4-point scale



**STATEMENT**  
**of the**  
**AMERICAN ASSOCIATION OF RETIRED PERSONS**

The American Association of Retired Persons (AARP) welcomes many of the President's initiatives included in the Health Security Act (HSA), H.R. 3600, to improve the quality of care. We believe that health system reform brings with it not only the challenge to preserve quality, but also the opportunity to set in place systems that will enable us to improve significantly and continuously the quality of American health care. The issues of quality and consumer protection go hand-in-hand, and many of the provisions of Title V of the HSA reflect a vision of a broad quality system, a vision that we wholeheartedly support. Several provisions of Title V were the subject of a hearing by this subcommittee earlier this week on the topic of consumer protection, and are addressed in the testimony of the "Coalition for Consumer Protection and Quality in Health Care Reform." The Association concurs with the recommendations included in the Coalition's testimony. Our comments here are focused on the discrete issue of quality assurance.

**ACCOUNTABILITY FOR QUALITY**

In a reformed health care system, consumers need to have a say not only in their selection of health plans, but also in governance and in assuring accountability throughout the system. AARP is supportive of HSA's provision that Alliance Boards of Directors be composed of equal representation by consumers and employers. This principle of substantial consumer representation

should be carried over to the Boards and Commissions established to oversee health care quality. For example, there is currently no provision for consumer representation on the National Quality Management Council; consumers should be a distinct category for representation on that important body.

HSA's extensive consumer information program, when fully implemented, will be a cornerstone of public accountability, a component which is sorely lacking in the current system. The program is welcome and needed. We must recognize, however, that it will take a long time, and a significant financial investment, to develop and implement the data systems which are envisioned. Many critical performance and quality measures--particularly those which measure the quality of care for those with chronic illnesses--have not been developed.

#### THE NEED FOR INDEPENDENT OVERSIGHT

While consumer information is an essential component in the overall quality assurance strategy, it is only one piece. Consumer information, particularly in its current state, cannot substitute for a coordinated system of independent quality oversight. Such oversight includes: (1) monitoring to assure a basic level of quality and detect patterns and significant instances of poor care; (2) quality improvement activities to

assist practitioners and plans in reaching quality levels achieved by the best performers; and (3) referrals to appropriate enforcement entities when action may be needed to protect consumers.

#### WHAT'S IN HSA AND WHAT'S MISSING

While taking a more comprehensive approach to quality assurance than any other proposal currently under consideration, The Health Security Act does not currently provide all the tools necessary for a comprehensive quality monitoring system. We believe that the quality assurance system must balance the need to improve the "mainstream" of care through non-punitive feedback of information to providers with the need to protect consumers from poor quality care. The Act does not identify any entity responsible for assuring a basic level of care and protecting consumers from poor quality care.

HSA does address quality improvement (as opposed to quality assurance or protection) through creation of "Regional Professional Foundations" based in academic medical centers. Such foundations are charged with developing programs of lifetime learning for health professionals, disseminating information and fostering collaboration among health plans and health care providers. While we believe that these are important roles which academic medical centers can and should play in a reformed health

care system, we do not believe they can substitute for a system of independent quality oversight that holds plans publicly accountable. Under the President's proposal, plans and providers would not be obligated to participate in the foundations' programs, and the foundations would not be obligated to work with particular health plans or communities. The foundations, comprised of and governed by representatives of academic medicine, would not be publicly accountable through a consumer-guided board of directors. Compared with state-based foundations (which were originally proposed), these regional level entities would also be more distant, and therefore less responsive to local needs.

#### RECOMMENDATIONS

We recommend that the Act be amended to include establishment of state-based quality organizations, governed by independent Boards of Directors, one-half of whose members represent consumers. These quality organizations would be charged with ongoing quality monitoring of all plans within their jurisdiction and would be able to hold plans accountable for quality of care. They would provide technical assistance tailored to the specific needs of each plan, in order to improve quality. Quality organizations could also be structured to provide independent medical review of care denials during the grievance and appeals process, and to investigate consumer complaints regarding the quality of care.



Such organizations would not have enforcement responsibilities, but would be obligated to refer appropriate information to licensure and other regulatory bodies for disciplinary action.

Experts tell us that quality improvement efforts are more successful if they come through an entity that does not also conduct disciplinary activity. Therefore, we propose that the authority for enforcement and discipline reside within the state medical licensure boards and other regulatory entities. However, in order to make enforcement more effective than it is today, the new system must find a way to obligate the state agencies to conduct timely and thorough investigations of reports of poor care, and to respond with appropriate sanctions. Such obligation must be accompanied by sufficient funding to do the job.

We applaud HSA's provision that requires the Secretary to develop regulations allowing access to information in the National Practitioner Data Bank on practitioners who have been subject to multiple reports. However, the language, which currently restricts access to "individuals seeking to enroll in health plans" under HSA, should be broadened to include any individual (such as a Medicare beneficiary). Medicare beneficiaries should have the same rights to information as alliance members. We further urge that any final disciplinary action that would be

public in another forum (such as action of a state medical licensure board) should be accessible by individuals through the Bank.

It is unclear from the context of HSA how the quality assurance provisions would apply to Medicare beneficiaries who continue to be covered under the separate Medicare program.

Nevertheless, the Act terminates the primary quality assurance program for Medicare beneficiaries. Specifically, it deletes the section of Title XVIII that authorizes the Medicare Peer Review Organization (PRO) program, including its appeal rights for hospitalized patients, without providing for any successor. An independent, external oversight body will continue to be needed in Medicare to assure that quality of care does not suffer, especially during a time of unprecedented budget cuts and rapid delivery system restructuring. The Association urges this committee to remove section 4031, which terminates PRO responsibilities for the Medicare program one year after enactment. If independent quality organizations are enacted and prove effective in improving quality and protecting consumers, consideration should then be given to assigning them the PRO responsibilities for Medicare quality assurance.

A comprehensive quality management program will need sufficient, reliable funding. Funding is needed not only for operation of the independent quality organizations, but also for the consumer

and practitioner information efforts and the related consumer grievance and appeals system and the ombudsman program. HSA should be amended to provide an explicit set aside as a percentage of premium to establish and maintain the program.

#### CONCLUSION

Accountability to the consumer for the quality of care will be an important accomplishment of health care reform. In a system that seeks to achieve a uniform nationwide standard of care, but is proposed to be managed by fifty different states and even more alliances, such public accountability and consumer participation in governance takes on heightened importance. Accountability will be enhanced through the establishment of state-based independent quality monitoring and improvement organizations that are governed by consumer-guided Boards of Directors. We urge the committee to embrace the good foundation for quality assurance created in HSA, and to improve it by incorporating the missing component of accountability through independent oversight.

Mr. BROWN. I think this is for any or all of you to answer. I think it is fair to say that the President's proposal doesn't address the full range of the long-term care needs, as particularly Ms. Canja indicated. However, given limited resources, the President in his plan has chosen as a first step toward comprehensive health care reform coverage accomplishments for home- and community-based services. My question is, is that the right priority and do the organizations that you represent seek coverage for home- and community-based care and services as the place to begin a more comprehensive coverage of all services? Mr. Young?

Mr. YOUNG. As far as CCD is concerned, yes. We think that the home- and community-based program is absolutely the place to start, and we think this is an excellent beginning for what will eventually be a comprehensive program of supports and services for people with disabilities of all ages.

Ms. REID. The Long-Term Care Campaign's organizations unanimously support that.

Ms. CANJA. What we have now is a system that is institutionally biased. This begins to level out the system. It also provides care where people really want to be in their own homes. So it is an appropriate first step.

Mr. BROWN. Yesterday, we had a hearing on the Cooper-Grandy bill, the H.R. 3222, the managed competition bill. Under that bill, the Medicaid program, including its coverage of nursing home and home- and community-based services, is repealed effective January 1, 1995. While there would be reduced Federal payments to States for long-term care services until 1998, there is no continuing Federal requirement for assistance for these benefits. Mr. Cooper said yesterday that he expects the States to assume the responsibility for financing these services and they would be able to take on this job with the savings they realized from the federalization of the acute care part of Medicaid. Is your view that the States will live up to his expectations?

Ms. REID. No. In Pennsylvania, I know that the State's—and we have a very progressive State—but there are so many other competitors for those dollars. There are roads. There is education. There are so many other issues, and I don't think that we will see that the States will be able to—will decide to use that money in this way. It gives them four options and it means that for people like me and millions of others, we are right back where we started from, and maybe even worse off.

Ms. CANJA. I can speak also from experience in Florida, knowing the financial straits, not just Florida, but many States have been in, and I could add to that list. Prisons are now very big and we are to find the money for all of this, and to free up a pot of money, you know, it is going to be very hard for legislators to continue a commitment to long-term care.

I am also thinking in answer to your question of the burden on consumer advocates. Right now we are doing everything we can to protect State programs for care. We are trying to develop in our State a long-term care system. I think Florida is not unique in really not having a rational long-term care system, and unless that is in place, unless there are some State guidelines that we are



going to do this, this is a priority, there is no priority for the money that would be released.

Mr. YOUNG. The Medicaid program as it is today represents many, many years of hard work on the efforts by advocates and policy-makers to try and build a—something of an infrastructure for supports and services for people with disabilities, and it would take—to have it go away with the stroke of a pen would take many, many years of much hard work again to try and rebuild.

Mr. BROWN. Ms. Reid, you mentioned single-payer for a moment, sort of in passing. Does the Alzheimer's Association support single-payer over the Clinton health plan?

Ms. REID. The Alzheimer's Association does support the Clinton health plan first. We feel that that is the most important program that will serve our community, our folks first.

Mr. BROWN. But you didn't really answer my question. Does the association not support single-payer or does it? You seem personally to like the idea, obviously.

Mr. MCCONNELL. Steve McConnell, Senior Vice President for Policy for the association. The association has taken a position in strong support of the President's long-term care portion of the health plan. We have not taken a position on any of the other aspects of the Clinton health plan or on any of the other plans, but we have evaluated all the plans and concluded that on long-term care, the Clinton plan meets our standards, as does the single-payer plan, but we have not commented on the rest of them.

Mr. BROWN. Ms. Reid, I would particularly like to compliment you. You must have interviewed a lot of politicians by the way you answered that question.

Ms. REID. I am a quick study.

Mr. BROWN. The gentleman from Ms. Reid's almost hometown, Mr. Greenwood from Pennsylvania is recognized for 5 minutes.

Mr. GREENWOOD. Thank you, Mr. Chairman.

Orien, would you walk us through your experiences when your mother came home with you, and in your attempts to find financial support for caring for her in your home or elsewhere?

Ms. REID. Well, back in 1988, the very first step after she was diagnosed with Alzheimer's disease, I thought that, well, she has been paying. I knew that she and my stepfather had been paying for Medigap insurance all of this time and I knew it was very expensive, so I assumed that we would get some kind of help there, and I discovered that there was no help there, that they didn't cover the kind of care that she needed.

The next thing I did was contact the Alzheimer's Association and ask them for a list of insurance companies, and I can't tell you the number of days that I spent on the phone calling insurance companies to see if there was any way that I could get an insurance policy that would help us out. That didn't turn out. So I finally—

Mr. GREENWOOD. That was because of her preexisting condition?

Ms. REID. Because of her preexisting condition, that there was absolutely no help for us.

Then at some point—in fact when my stepfather was sick, I could never convince either one of them that she was really sick, even though a diagnosis had been made. So when he was in the hospital, it was just inconceivable of having them pay for home health care

because she believed she could stay at home by herself, so I assumed that responsibility. And this went on for several months while my stepfather was in the hospital.

When my stepfather finally died, by that time I had oriented my mother and said, you know, you will never have to worry. You are going to come and live with me, and she was very comfortable with that. So I went to Atlanta, brought her back, as I said. We caught—I will never forget this, a 6 a.m. flight out of Atlanta so that I could be at work at 9 a.m. and I showed up at work with my mother and I took her with me because I hadn't even had time to look into what I was going to do with her during the day while I had to work.

And I continued to do this until I could find day care, and the first day care facility I found, she wasn't happy with it, and that was important to me. I found a second day care facility that cost \$32 a day. She spent 3 days a week in day care. She wanted to spend some time at home and I wanted to honor, because she did have a choice, and I had to consider her. So I hired a home health aide for her and this went on for a 1½ years.

Mr. GREENWOOD. Was Pennsylvania participating voluntarily in the Medicaid program that would provide assistance?

Ms. REID. My mother didn't qualify. My mother didn't qualify for any assistance. She didn't qualify. She was just over the limit for our PACE program, which was the prescription drug program, which meant even our medicines were all out of pocket.

Mr. GREENWOOD. Was she working? Did she have income from your father's pension or something?

Ms. REID. She had some income from—it totaled, OK, about \$1,100 a month. That was it. That was all she got from social security. She got \$300-some from her pension, and \$800 from social security, so that was it. That was the extent of our—of her income, and the rest of this had to be supplemented.

When I moved her into a nursing home, as I said, it was \$100 a day just for the nursing home. It did not include all of the ancillary services that go with a nursing home, and when somebody mentioned—you mentioned a mortgage, I used to think of it as a second mortgage because I was looking at \$1,500 to \$1,700 or more a month for the nursing home while she was there. It was very difficult.

Mr. GREENWOOD. Thank you. This is an editorial comment. You mentioned the fact that you were concerned that when we struggle with this issue of the Federal versus the State responsibility for long-term care, that you feel that the States won't assume the financial responsibility because of their competing demands.

Having spent 12 years in that legislature and having been involved in that, I can tell you that the only difference between here and there is they have to balance their budgets; we don't. We borrow trillions of dollars and it makes it a little easier for us to make that choice.

And you talked about the concern that you were spending down your children's college education. What we are engaged in in this town is spending down all of our children's future, so we have some real policy struggles to deal with. Thank you.

Ms. REID. Thank you.

Mr. BROWN. Thank you, Mr. Greenwood. The gentleman from Connecticut, Mr. Franks.

Mr. FRANKS. Thank you, Mr. Chairman. My colleague, Mr. Greenwood, hit upon a very key point and I think you did as well, Ms. Reid, that being the preexisting condition element of your situation prevented you from being able to purchase any type of long-term health insurance.

In our State of Connecticut, and I believe in about three or four other States, we strongly advocate the use of long-term insurance, but if you are looking at a preexisting condition-type situation, it does create a problem. But I don't believe that anyone would find any objections on either side of the aisle on that issue. I think we should look at the preexisting situation as being one in which we change immediately.

Second, if we were able to make that change and also offer some kind of long-term insurance coverage, how would—I believe that those two changes in itself could have addressed your situation within a very favorable light instead of looking at the prospects of a single-payer type system, which you spoke favorably of. Obviously, the organization may not have an opinion on that but you did speak very favorably of that proposal, and/or the proposal mentioned by the President. I believe that those two changes in itself would have addressed your situation rather well. If you disagree or there are any comments you would like to make to that, I would like to hear them.

Ms. REID. It certainly would have, as long as the long-term care insurance was affordable for all. I certainly would have been willing to pay something to help take care of my mother, pay a fair share, and I think it is very possible that with—for people of all incomes on a sliding fee scale, that you can have some participation in this.

Mr. FRANKS. And also, I am a strong advocate of some type of tax relief for individuals that would opt to purchase long-term insurance. So I am not, as you can tell, I am not a supporter of the single-payer system and I am not—I agree with the President on many of his proposals within his plan, including the preexisting condition change, but I believe that situations like yours and others can be handled by eliminating or addressing the preexisting condition problem and also looking at the Connecticut plan and the California plan and Indiana plan that will address long-term insurance coverage as well as looking at tax relief for those individuals who will take advantage of such a plan.

Yield back the balance of my time, Mr. Chairman.

Mr. WAXMAN. Thank you very much, Mr. Franks.

I want to thank each of you for your testimony today. You have given us very useful, important information which we will have in the record to share with our colleagues.

Our second panel includes various providers of long-term care services. Mr. Ken Wessel is Executive Director of the Visiting Homemakers Service of Passaic County, N.J. He is testifying on behalf of the National Association for Home Care. Ms. Sharon Grigsby is President of the Visiting Nurse Associations of Los Angeles and is appearing on behalf of the Visiting Nurse Associations. Gerald A. Born is Administrator of the Division of Community



Services with the State of Wisconsin's Department of Health and Social Services. Appearing on behalf of the PACE program, the program for All-Inclusive Care for the Elderly is Ms. Marie-Louise Ansak. And we will also hear from two representatives from the nursing home industry, Dr. Paul Willging, an Executive Vice President of the American Health Care Association, and Dr. Sheldon Goldberg, President of the American Association of Homes for the Aging.

We are pleased to welcome you to our hearing today. Your prepared statements will be in the record in full. What we would like to ask of each of you is to limit the oral presentation to no more than 5 minutes. If the bell rings and we run out of time, don't worry that we won't have the information you wanted in the record because we are going to include your written statements in full, but we are going to have to be very strict about the 5-minute rule in order to be fair to everybody and to get through the hearing.

We are pleased to have all of you here. Let us hear first from Mr. Wessel.

**STATEMENTS OF KEN WESSEL, MEMBER, GOVERNMENT AFFAIRS COMMITTEE, NATIONAL ASSOCIATION FOR HOME CARE; SHARON FLYNN GRIGSBY, PAST CHAIR, VISITING NURSE ASSOCIATIONS OF AMERICA; GERALD A. BORN, ADMINISTRATOR, DIVISION OF COMMUNITY SERVICES, WISCONSIN DEPARTMENT OF HEALTH AND SOCIAL SERVICES; MARIE-LOUISE ANSAK, FOUNDING EXECUTIVE DIRECTOR, ON LOK, INC., ON BEHALF OF THE PROGRAM FOR ALL-INCLUSIVE CARE FOR THE ELDERLY; PAUL R. WILLGING, EXECUTIVE VICE PRESIDENT, AMERICAN HEALTH CARE ASSOCIATION; AND SHELDON L. GOLDBERG, PRESIDENT, AMERICAN ASSOCIATION OF HOMES FOR THE AGING**

Mr. WESSEL. Thank you. My name is Ken Wessel. I am the Executive Director of the Visiting Homemakers Service of Passaic County, a nonprofit home care provider in New Jersey. I am currently the Chair of the National Accreditation Commission of the National Home Care Council and a member of the Government Affairs Committee of the National Association for Home Care, NAHC.

NAHC, which represents the Nation's home care providers and the individuals they serve, has long advocated the development of a national plan to ensure universal access to basic acute care and long-term care services. We are particularly pleased to be here today to share our views with Chairman Waxman and the other members of the committee regarding the home- and community-based long-term care program that President Clinton has proposed.

To have meaningful reform in our Nation's health care systems, the members of NAHC, like many of you, believe that making long-term care services affordable and accessible is imperative, especially if we are going to protect the American people against the staggering financial and human costs associated with providing long-term care to our Nation's chronically ill and disabled citizens. Clearly, current public programs and private insurance are inadequate to meet the country's growing need for long-term care.

We believe that the home- and community-based long-term care component of the President's plan is one of its strongest provisions



and sets it apart from the whole host of current health care reform proposals that have neglected to seriously address the long-term care issue. We are especially pleased that the President's long-term care program does not exclude individuals on the basis of age or income, but instead qualifies them for services on the basis of need. Second, we are pleased this proposed legislation does not require States to use costly external case management procedures that duplicate standard caregiver activities.

In order to qualify for service under the Clinton plan, individuals would have to either need assistance with at least three activities of daily living, have severe cognitive or mental impairment, have severe or profound retardation, or for children under the age of 6, be dependent on technology and otherwise require hospital or institutional care.

Fewer than one-third of the 10 million disabled people who live in community settings and need long-term care would qualify for care under these eligibility criteria. NAHC urges Congress to work with the administration to lower this standard to make long-term care available to all individuals in need of it.

NAHC is concerned with the amount of flexibility States will be given to implement this program, especially the amount of discretion the States will have in determining the level of benefits. NAHC recommends strengthening the existing language by requiring the full range of home- and community-based services be offered to all eligible individuals regardless of the State in which they reside.

We support the plan's requirement that no more than 10 percent of a State's expenditures are used for State administrative costs. Given the already scaled back nature of the long-term care program, it is important that precautions are taken to ensure that funding goes towards providing actual services.

While there is no requirement that the States use external case management services, there is likewise no recognition that provider-based case management is a viable method of furnishing these services.

NAHC has consistently supported permitting home care agencies to perform case management functions. Case management has always been an integral part of the caregiving process and is a responsibility that agencies have performed for more than a century.

The General Accounting Office studied various methods of case management in six States and was unable to identify any studies or evaluation that showed one system to be more effective than another.

A number of States successfully utilize provider-based case management, or have positive collaborative relationships in place. New Jersey, for example, uses a medical-social model of case management with an interdisciplinary approach for its Medicaid, home- and community-based services program.

Many case management providers under the program are home care agencies. Home care agencies have firsthand intimate knowledge of their client needs and are currently performing case management activities to a large extent. We urge clarification of this provision of the President's plan to ensure a role for home health

agencies as case managers. Our agency is a case manager for a respite plan in New Jersey and a provider.

With respect to involvement of paraprofessionals like home care aides in the delivery of long-term care services, NAHC supports standards for training, testing and supervision of these workers. The National Association of Home Care has written a white paper on that very issue, Levels of Care, and that is available to the committee, if you would like it.

State certification of these workers should be ensured so that all home care aides are appropriately trained, tested and supervised. Quality assurance standards should be applied to the delivery of services in the home regardless of the source of payment.

The Clinton plan at the very least represents an important step in the right direction. The members of NAHC anticipate that the President's plan will be a foundation for long-term care that is reliable and progressively financed. It will also serve all people regardless of income and age. We look forward to working with the members of the administration and Congress towards this end.

Mr. WAXMAN. Thank you, Mr. Wessel. Appreciate your testimony.  
[The prepared statement of Mr. Wessel follows:]

## Testimony

of

Ken Wessel, Executive Director

Visiting Homemaker Service of Passaic County

My name is Ken Wessel. I am the Executive Director of the Visiting Homemaker Service of Passaic County in Paterson, New Jersey and a member of the Government Affairs Committee of the National Association for Home Care (NAHC). NAHC, which represents the nation's home care providers -- including home health agencies, home care aide organizations, and hospices -- and the individuals they serve, is committed to ensuring the availability of humane, cost-effective, high quality home care services to all individuals who require them. NAHC has long advocated the development of a national plan to ensure universal access to basic acute care and long-term care services. We are particularly pleased to be here today to share our views with Chairman Waxman and the other members of the Energy and Commerce Committee regarding the home- and community-based long-term care program that President Clinton has included in his health care reform package, the Health Security Act.

Let me begin by saying that we have been encouraged by the remarks many Members of Congress and the Administration have made on the need to include long-term care in any health care reform proposal passed by Congress. To have meaningful reform in our nation's health care system, the members of NAHC, like many of you, believe that making long-term care services affordable and accessible is imperative -- especially if we are going to protect the American people against the staggering financial and human costs associated with providing long-term care to our nation's chronically ill and disabled citizens. Clearly, current public programs and private insurance are inadequate to meet the country's growing need for long-term care services.

NAHC has given qualified support to the Clinton health care reform proposal. We wholeheartedly support the goals of guaranteeing access to high quality, affordable care to all Americans and simplifying the current health care system. Our endorsement extends to the specifics of the Clinton reform plan that are consistent with the top three priorities established by our membership last year: (1) the plan preserves the Medicare program; (2) home care is part of the acute care benefits package; and, (3) the plan includes a new comprehensive long-term care benefit based on home care. We believe that the home- and community-based long-term care component of the President's plan is one of its strongest provisions and sets it apart from the whole host of current health care reform proposals that have neglected to seriously address the long-term care issue. We are especially pleased that the President's long-term care program does not exclude individuals on the basis of age or income, but instead qualifies them for services on the basis of need. Second, we are pleased his proposed legislation does not require states to use costly external case management procedures that duplicate standard caregiver activities.

### Eligibility Criteria

In order to qualify for services under the Clinton long-term care proposal, individuals would have to either need assistance with at least three of the five activities of daily living (bathing, dressing, transferring, toileting, and eating); have a severe cognitive or mental impairment; have severe or profound retardation; or, for children under the age of six, be dependent on technology and otherwise require hospital or institutional care. Fewer than one-third (3.1 million) of the 10 million disabled people who live in community settings and need long-term care would qualify for care under these restrictive eligibility criteria. Millions of individuals of all ages and disabilities who are in need of long-term care would not be helped by this program.

NAHC urges Congress to work with the Administration to lower this standard and make long-term home care available to all individuals in need of this care. Specifically, NAHC recommends lowering the criteria so that all individuals who need assistance with one or more activities of daily living (ADLs) and all those with cognitive or mental impairments are eligible for assistance. In this way, the plan will reach more than just the most severely disabled citizens of our nation. NAHC members have consistently voiced their support for a broad-based progressive financing method to fund a national long-term care program, including such necessary improvements.

### The Role of the States

The Clinton home- and community-based long term care program will be administered as a block grant program. NAHC is concerned about the amount of flexibility states will be given to implement this program. Specifically, we are concerned about the amount of discretion the states will have in determining the level of benefits. We believe this could lead to an inequitable situation in which benefits vary greatly from state to state. To make the program more equitable and uniform, NAHC recommends strengthening the existing language by requiring that the full range of home- and community-based services be offered to all eligible individuals regardless of the state in which they reside. These services should include nursing care; home care aide services; medical social services; personal care services; chore services; physical, occupational, speech, and respiratory therapy and rehabilitative services; hospice services; respite care; adult day care; medical supplies and durable medical equipment; minor home adaptations that enable beneficiaries to receive services at home; transportation services; nutritional services; and patient and family education and training. This list, while extensive, represents the appropriate kinds of services that should be available to all Americans under a national long-term care program based on home- and community-based care.



As long as the President's home- and community-based long-term care proposal remains a block grant program, the states will have considerable control over their own expenditures. For this reason, we support the plan's requirement that no more than 10 percent of a state's expenditures are used for state administrative costs. Without such an assurance, a disproportionate amount of money could be diverted from patient care. Given the already scaled back nature of the President's long-term care program, it is important that precautions are taken to ensure that funding goes toward providing actual services.

### **Case Management**

The President's plan does not specify the form in which states may choose to implement optional case management services. While there is no requirement that the states use external case management services, there is, likewise, no recognition that provider-based case management is a viable method of furnishing those services. For several reasons, NAHC has consistently supported permitting home care agencies to perform case management functions. First, case management has always been an integral part of the caregiving process, and is a responsibility that agencies have performed for more than a century. Second, payors and providers of service have different goals for case management as performed by an external entity. Experiences vary widely in states currently providing case management services with no one model emerging as ideal.

The General Accounting Office, in its report of April, 1993, *Long-Term Care Case Management: State Experiences and Implications for Federal Policy*, states that after studying various models of case management in six states it was unable to identify any studies or evaluations that showed one system to be more effective than another. In our own observations, there are many successful models which either require or permit provider-based case management. They include the Medicare home health benefit, the Medicare hospice benefit, the demonstration Social HMO projects, the demonstrations under P.A.C.E. (Program for All-Inclusive Care for the Elderly; also known as OnLok), and Medicaid Home- and Community-based Waivers.

A number of states successfully utilize provider-based case management, or have positive collaborative relationships in place. In Connecticut, for example, a one year demonstration project was conducted in 1992, sponsored by the Department on Aging, to determine whether provider case management could be cost-effective, without succumbing to self-interest while meeting established goals. The project was a success as reflected in a letter from the State of Connecticut to one of the home health agency participants. It states in part, "the need for administrative overhead associated with additional layers of case managers was eliminated in its entirety without adverse effect on the client population."

New Jersey utilizes a medical-social model of case management with an interdisciplinary approach for its Medicaid home- and community-based services program. The sites are chosen through a Request For Proposal process, using interviews and definitive guidelines. A mixture of agencies serve as sites, but the predominant case management providers are home health agencies. In Iowa, case management is technically assigned to the Area Agencies on Aging. However, by regulation, an interdisciplinary team case conference is required, which includes the home care agency, to develop the plan of care for the client.

Case management, among other purposes, serves to enhance communication and coordination of services. Home care agencies have first-hand, intimate knowledge of their clients' needs, and are currently performing case management activities to a large extent. We urge clarification of this provision of the President's plan to ensure a role for home health agencies as case managers.

### **Special Delivery Issues**

With respect to involvement of paraprofessionals, like home care aides, in the delivery of long-term care services, NAHC supports the standards for the training, testing, and supervision of these workers as established by the Joint Commission on Accreditation of Healthcare Organizations, the Community Health Accreditation Program and the National Homecaring Council. As it is currently written, the President's home- and community-based long-term care program would allow consumers to select their own caregivers, but would not establish any standards or regulations regarding these caregivers. State certification of these workers should be ensured so that all home care aides are appropriately trained, tested, and supervised.

Finally, provisions enabling the use of vouchers to purchase home care services, or direct payments by patients to individuals providing home care as envisioned in the Clinton plan, should be prohibited. Individuals should be encouraged to purchase services from qualified home care agencies that can control the quality and utilization of services, protect vulnerable patients, ensure adequate training and supervision of home care personnel, and provide employee benefits. This practice would diminish the potential for fraud and abuse by holding agencies responsible for all facets of their patients' care -- financial as well as medical.

This recommendation is also consistent with the program's need to ensure quality of care. Quality assurance standards, including minimal standards of training, testing, and supervision should be applied to the delivery of services in the home, regardless of the source of payment for those services. The requirements contained in the Medicare conditions of participation for home care and hospice should be applied to the delivery of in-home long-term care services where appropriate.

NAHC believes that the home- and community-based long-term care plan proposed by President Clinton can be strengthened to ensure the delivery of comprehensive, quality home care services to all those in need. Nonetheless, we want to reiterate that the Clinton plan at the very least represents an important step in the right direction. The members of NAHC anticipate that the President's plan will be the foundation for a long-term care program that is reliable and progressively financed for many years to come and serves all people regardless of income and age. We look forward to working with members of the Administration and Congress toward this end.

Mr. WAXMAN. Ms. Grigsby.

# STATEMENT OF SHARON FLYNN GRIGSBY

Ms. GRIGSBY. Mr. Chairman and committee members, thank you for this opportunity to discuss the President's Health Security Act provisions for home- and community-based services for individuals with disabilities.

My name is Sharon Grigsby and I am the President of the Visiting Nurse Association of Los Angeles and Past Chair of the Visiting Nurse Associations of America on whose behalf I am here today.

Mr. Chairman, I bring you greetings from the very shaky region you represent and bring also our thanks to all of you for the significant and very effective Federal presence in Los Angeles after our recent earthquake. With our President and members of the Cabinet and many of our elected Representatives present and demonstrating your support, recovery efforts have gotten under way very quickly.

As part of these recovery efforts, the Los Angeles Visiting Nurse Association was asked to staff Red Cross emergency shelters with our nurses. I have been out to several of these shelters talking with the residents and with our staff. The spirit and resilience of Angelinos, both those directly affected and those helping out, would inspire you as it has me.

After the tours, however, I must report that the much stretched health care safety net now has a few new holes. Loss of three of our major inpatient facilities, especially those serving the indigent and veterans, are a great loss to the people of San Fernando Valley. Our health care system, especially as governmentally funded, uses these hospitals as the hub of health care services for their respective populations. With the quake, not only are these facilities gone but the support systems, ambulance and Medivan transportation, outpatient treatment, rehab and pharmacy services, are disrupted or disappeared. The lost looks on the faces of the people in the shelters reflect the enormity of the task they face in putting their lives back together. For the frail and elderly and disabled, that task is even greater.

While they struggle with housing and food, what happens to that previously scheduled appointment for their hypertension, their diabetes, their pulmonary disease, their heart condition? With their hospital closed, they will try to do without until things settle down or until someone has to call 911 for them or rush them to the emergency room.

I believe the Los Angeles quake illustrates a very serious structural flaw in our health system and that is the subject of our hearing today.

In our formal written testimony to the committee, we expressed five concerns for a new long-term care program. First, there is an urgent need to implement a national comprehensive long-term services program to complete the continuum of service necessary to manage the health care status of our elderly and disabled population; second, a minimum set of benefits should be offered to eligible patients in each State delivered to federally established standards; third, the financing for the long-term care program must be adequate to assure quality, access to care and patient choice, while



protecting patients and the government from profiteering; fourth, professional case management is the most effective way to coordinate cost and care for chronically ill patients. We must not duplicate existing regulatory requirements to do this; and fifth and finally, a research component should be built into the program to determine optimal functional outcomes and the effectiveness of our eligibility requirements of deficits in three ADL's. Each of these points is developed further in our paper, but I greatly fear we will never get to the content of this essential program.

Based on more than 100 years of experience in home care and on serving millions of Medicare and Medicaid beneficiaries, Visiting Nurse Associations bring you an urgent plea. Please do not allow the debate on long-term care to be framed as simply the analysis of a new and costly benefit. You have the power to use this forum to focus on the real issue in long-term care, and that is the needs statement from those persons who make up the fastest growing, most complex and most expensive health care consumers, persons with serious and persistent chronic illnesses.

Our present health care system is a forced fit for them at great cost to them and to us. Their care resources are emergency rooms, acute inpatient facilities and nursing homes. True, long-term care would manage these chronic cases to intervene before the 911 call to prevent delay and minimize the progression which tends to characterize these situations.

Inpatient care in nursing homes would be accessed only when no other source of care would be appropriate to meet their needs. Without a commitment to meeting these needs in the most cost-effective way, through an integrated, acute home- and community-based care program, there can be no real health care reform. Rational comprehensive managed long-term care is now the missing piece and attempting health reform without long-term care is merely rearranging the deck chairs.

The voluntary nonprofit Visiting Nurse Associations of America urgently request that you take up the challenge of health reform and fight for the necessity of appropriate long-term care as a necessary prerequisite to achieving the quality, access and cost containment goals of this health reform effort.

Thank you.

Mr. WAXMAN. Thank you very much, Ms. Grigsby.

[The prepared statement of Ms. Grigsby follows:]



Testimony of Sharon Flynn Grigsby, President  
Visiting Nurse Association of Los Angeles

**Introduction**

My name is Sharon Flynn Grigsby. I am President of the Visiting Nurse Association of Los Angeles, and past chair of the Visiting Nurse Associations of America. We are pleased to be invited to present before this subcommittee our views on President Clinton's "Health Security Act," Title II, Subtitle B, Part 1 -- State Programs for Home and Community-Based Services for Individuals with Disabilities.

**Summary of Recommendations**

In this testimony we will offer Visiting Nurse Associations' (or "VNAs") credentials of more than 100 years' experience providing non-profit home care in this country. Based on this experience, we would like to make five recommendations for your subcommittee's consideration.

First, there is an urgent need to implement a national comprehensive long-term care program to complete the continuum of services necessary to manage the health care status of our elderly and disabled populations.

Second, a minimum set of benefits should be offered to eligible patients in each state.

Third, the financing for the long-term care program must be adequate to assure quality, access to care and patient choice, while protecting patients and the government from profiteering.

Fourth, professional case management is the most effective way to coordinate cost and to care for chronic patients.

Fifth, and finally, a research component should be built in to the program to determine optimal functional outcomes and the effectiveness of the three activities of daily living (ADLs) deficits eligibility requirement vs. one or two ADLs.

These recommendations will be discussed and developed in the body of this testimony.

### **Visiting Nurse Associations' Background and Credentials**

Over 100 years ago, Visiting Nurse Associations embarked on a mission to provide compassionate, high-quality home and community care to people of all ages regardless of their ability to pay. As early as 1885, VNAs recognized that providing both health care and assistance with daily activities in the home helped people get well. VNAs are proud of their volunteer Boards' leadership in their communities, which assures that each community's individual needs are identified and addressed.

During the past century, VNAs grew from organizations providing basic health and hygiene care for a relatively small indigent and immigrant population, to today's provision of comprehensive, multi-disciplinary services to people of all ages in the home.

Originally, VNAs' primary mission was to lower infant mortality and to combat infectious diseases. They provided poor families with milk, basic nutrition, and nursing care. As more preventive and curative health services became available, VNAs were able to treat children and adults suffering from a wide range of health problems, which kept them temporarily or permanently home-bound.

Today, VNAs constitute a national network of approximately 500 community-based, non-profit, Medicare-certified home health agencies. While retaining their public health orientation, VNA services now range from skilled nursing and mental health care to hospice service, social work and physical therapy. High-tech services previously provided only in hospitals, such as ventilator care, blood transfusions, pain management and home chemotherapy are now routinely provided by VNAs. Although comprising less than ten percent of all certified home health agencies, VNAs might be called the government's unanointed home care partner since we provide about half of all Medicare home visits and over three-quarters of all Medicaid home visits. VNAs also carry a significant share of privately-insured home care and the bulk of indigent care. VNAs have special expertise in working with complex patient care needs, including poor women at-risk for delivering premature infants, HIV patients, individuals with chronic disabilities and elderly patients requiring long-term care. The fastest growing segments of the VNA patient population are the dependent elderly over 80, and chronically ill children under age five.

VNAs have been, and continue to be, the safety net for patients who are denied services, either because they are not poor enough to qualify for Medicaid, because Medicaid or Medicare do not fully cover the services they need, or because they are uninsured, underinsured, or have exhausted their insurance. Charity support from the United Way and other philanthropic sources is what allows us to be that safety net. Charity giving is used to pay the difference between cost of care and reimbursement. However, the level of charitable contributions has been severely affected by the recent economic downturn. VNAs also are feeling the impact of Medicare cuts from the 1993 Omnibus Budget Reconciliation Act.

By history and practice, VNAs have a long-term care focus and help their chronically ill and disabled patients bridge the gap between these needs and the rigidities of our acute, short term care driven health system. Accordingly we believe VNAs have both experience and commitment to offer in the construction of the much needed new long- term care program.

### **Rationale for Recommendations**

We commend the Administration for recognizing that the heart of health care reform is long-term home and community-based care. If we, as a nation, are to move beyond our acute care focus and achieve both universal access and cost-containment, **we must have expedient implementation of this Act, and this program.** The following are our recommendations for a long-term care program:

1. There is an urgent need for a national comprehensive long-term care program to complete the continuum of services necessary to manage the health care status of our elderly and disabled populations.

Lacking a long term care component, the present health system forces the chronically ill and people with disabilities to access care through the most costly channels: emergency rooms and acute hospitals. In our current system, long term care is equated with nursing homes. **Of the \$53 billion the nation**

spent on long term care in 1988, according to the Pepper Commission report (1990), only 18% of these services were provided in the home. Yet four out of five people with disabilities live at home.

Every day VNAs see Medicare patients who must be discharged from hospitals because their conditions have reached a chronic state and skilled care will no longer be covered by Medicare. These patients typically have one or more chronic conditions and our experience is that within three to six months the patient will decompensate and require rehospitalization. These same patients will then be readmitted to home care following hospital discharge. This revolving door phenomenon is painfully common and frightfully expensive! The gaps in the health care system are nowhere more evident than in the chronically ill and disabled populations. All too often their only recourse is institutionalization. Most patients prefer to stay in their own homes. By implementing a comprehensive long-term care program, Congress will have plugged this costly gap in our health care system. A well-planned long-term care program will require coordination of services and integration of care along the full spectrum of health providers. Done properly, long-term care will move patients smoothly and effectively through the health care system, spending only the minimum required time in inpatient environments and maximizing caregiving in the community.

A successful long-term care program must address current trends and future inevitabilities including an aging population; earlier hospital discharges; increased patient survivorship due to new medical breakthroughs and high-technology equipment and services; and the growing incidence of Americans with AIDs. In addition, an increasing number of family members, particularly women, who traditionally provided home care, are being pressed by economic conditions to enter the workforce. Access to comprehensive long-term home care is essential to preserve health care dollars by the most appropriate use of each level of care.

2. A minimum set of benefits should be offered to eligible patients in each state. VNAs believe that the federal government should require a uniform minimum set of services that must be offered to



patients defined as eligible by federal standards. Services that states should provide include home health care not already covered by the skilled portion of Medicare, Medicaid, or by another health plan; case management; homemaker and chore assistance; home modifications; respite services; assistive devices; day care services for impaired adults and children; habilitation and rehabilitation; supported employment; and any other care or assistive services that are determined to help people with disabilities to remain in their homes and communities.

3. The financing for the long-term care program must be adequate to assure quality, access to care, and patient choice while protecting patients and the government from profiteering.

In pursuit of quality concerns, licensing and accreditation should be required for long term care providers. We advise caution in developing the needed federal/state partnerships so that requirements are not duplicated and that quality can be assured without instituting unnecessary bureaucracy.

With regard to methods of reimbursement, VNAs believe states should establish a mechanism to ensure that providers do not prosper at patients' expense, yet are reimbursed at fair market rates. **We want to be sure that any reimbursement method is well thought-out, so access to care and quality of care are not curtailed.** By contrast, in too many states the Medicaid home health program is heavily subsidized by providers. The fact that VNAs do 80% of Medicaid home care suggests that Medicaid providers are disproportionately non-profits. This program must ensure that rates fully cover the reasonable cost of providing care. The for-profits will not accept patients for less, and the non-profits are already using all their charity dollars for free and subsidized intermittent care services. VNAs do not have a "pot of money" to carry a providers' share of cost for this new program. VNAs strongly caution against building into the long-term care effort yet another federal program that depends on charitable organizations' subsidies to succeed.

VNAs recognize and support the plan's offer to eligible consumers the ability to contract for personal assistance services. Autonomy and choice in this option are important to people with disabilities.

However, VNAs are concerned that, without some regulation of these providers, consumers might receive substandard, or worse, hazardous care. Quality of service remains the heart of the issue. For patient choice to be effective, objective indicators of quality must be available, measured, and published. Significant conflict can arise around the issue of patient autonomy versus the cost of the bureaucracy created by imposing quality measures. Compliance with all the regulatory and quality standards costs money. If a patient takes the "low bid" and hires a minimum-wage, unbenefitted worker, the federal long-term care program would be blamed for horror stories that could result. **We believe that consumers should be able to contract independently for personal assistance, but with providers who have met appropriate certification requirements and who receive benefits accorded to employees, such as FICA and workers' compensation.**

In financing the program, the Act would require patient cost-sharing. VNAs see so many patients living at the economic margin for whom even a minimal share of cost would be prohibitive. If cost sharing is implemented, we believe that there needs to be a stop-loss mechanism so that patients and their families do not have to choose between impoverishment and foregoing care. Stop-loss levels should be created as limits to how much patients are assessed for their care. We also believe that mechanisms for determining individuals' income be appropriate, sensitive and consistently applied.

The program's financing mechanisms also should address the availability and cost of long-term care insurance. Effective use of tax incentives could draw additional private support, increase consumer choice and decrease the financial burden on government.

VNAs would point out that the Medicare home health program sustained significant cuts this year through reductions in Medicare cost limits, and by a two-year freeze on these limits. Further cuts in the Medicare home benefit to pay for this new program would result in two weak federal health care programs. Effective implementation of the reform plan should help eliminate overutilization and duplication of service, the savings from which could help support the new benefit.

4. Professional case management is the most effective way to coordinate cost, and to care for chronic patients.

Most experts agree that the complexities of chronic illness are best served through case management. Debate rages, however, as to how this should be done. Some feel that providers have a conflict of interest and should be excluded from this process. VNAs believe that the providers' ethical, regulatory and liability concerns require them to do it and anyone else who does it, duplicates effort and cost. Medicare requires a full assessment by the clinical professional admitting the patient to care and developing the plan of treatment. This also is required under many state licensing regulations, Medicare's Conditions of Participation, and by national accrediting bodies. In addition, most of our staffs believe that their professional credentials rest on the quality of their assessments in determining patients' plans of care. Thus, home health agencies must perform a full assessment before beginning care. This assessment is the starting point for managing the case.

Others call for "independent case management," precluding home health providers who are ultimately responsible for the patients. This group offers the "fox in the hen house" argument and postulates that case management be done by staff responsible to a case management company whose services are paid for by the case management company, insurance company, federal program, or another payor source. It is difficult to believe that such a structure can be expected always to act in the best interest of the patient. Rather than argue who has the bigger conflict-of-interest, the long-term care system should be designed so that the patient's needs are central and so that no one can profit by defining those needs to their personal benefit. One means of doing this is to capitate the population, assuming that quality care standards are being measured and met. The provider must then manage the patient's case within the dollars allowed. Over-utilization under capitation would benefit no one. VNAs urge that case management be built in to the long-term care program without redundancies in assessments, which create duplicate effort, drive up cost and burden the patient.

5. A research component should be built in to the program to determine optimal functional

outcomes and the effectiveness of the three or more activities of daily living (ADLs) screen versus one or two ADLs.

The program bases eligibility on patients with three activities of daily living (ADLs) deficits. VNAs are concerned that patients who depend on home care to remain out of nursing homes, and who are defined with only one or two ADL deficits, might be excluded. Most chronically ill patients experience progressive deterioration. By using three ADLs as the trigger for long-term care eligibility, the program may lose the ability to intervene earlier and perhaps slow the progression. Alternatively, a stair-step program with minimal service intervention for people needing assistance with one ADL, and additional services for those needing assistance with more than one ADL, might delay the need for institutionalization. VNAs propose that the program be implemented with a research component to determine the best functional measures for program eligibility. We need to be sure that we are accurately identifying a population of people who can be helped by long-term home care. We believe this research should be ongoing to test and fine-tune eligibility criteria, and to determine optimal functional outcomes. We recognize that needing assistance with three ADLs has been the traditional definition of need in the past. VNAs do not believe that this definition is the sole determinant of need. **There are some ADLs that are more critical than others.** We should not limit our solutions for the future by untested reliance on indicators from the past. Sound research is necessary to establish best practice.

### **In Summary**

We appreciate the opportunity to present our views and concerns. We realize that the subcommittee and Congress have a monumental task of creating the best and most affordable health care system for all Americans. We hope that you will continue to call on VNAs as you work in areas where our experience may be helpful to you.

For additional information regarding Visiting Nurse Associations of America, please feel free to contact Bill Varnell, President and Chief Executive Officer, VNAA, 3801 E. Florida Avenue, Suite 900, Denver, Colorado 80210, 303-753-0218.



Mr. WAXMAN. Mr. Born.

### STATEMENT OF GERALD A. BORN

Mr. BORN. Thank you, Mr. Chairman, I am Gerald Born, representing the Wisconsin Department of Health and Social Services. I am pleased to have the opportunity to talk about Wisconsin's experience in community-based long-term care and the proposed long-term care portion of the Health Security Act.

There are two reasons we have been in the forefront of long-term care reform. First, there is broad support in Wisconsin for public efforts to address the devastating effects of long-term chronic illness and disability on the social and economic well-being of families. Governor Thompson has led a significant expansion of home- and community-based long-term support programs for the elderly and other adults and children who experience chronic physical, mental or developmental disabilities. We are pleased that Congress and the Federal administration will be examining the need and the value of a nationwide system of long-term care based on consumer choice.

The second reason States like Wisconsin have been the leaders in long-term care reform has been the rising cost of an unmanaged institutional long-term care entitlement financed under title XIX. Governor Thompson and his predecessors have realized that long-term care costs will go up no matter what they do because of the dramatic rise in the population over age 85, the rising survival rates of adults and children with the most severe disabilities, and the rise in nursing home costs. Perhaps most remarkable about our efforts in the long-term care field is that it has been a marriage of cost control strategies and the pursuit of improved quality for consumers.

Wisconsin has developed a State-funded community options program, subsequently adding a Medicaid home- and community-based waiver, to support in their homes individuals who otherwise would qualify for care in a nursing home.

Community Options is administered by county agencies who serve about 13,000 individuals each year. Consumers pay a portion of costs on a sliding scale. Participants receive a comprehensive assessment of their resources and needs from a nurse and a social worker, a care plan which reflects consumer preference for types and location of services, and authorization for services from a wide variety of formal and informal providers. Community Options will pay for anything identified in a care plan as necessary to enable the person to remain at home. There is no limiting schedule of benefits or authorized providers and maximum flexibility and consumer responsiveness is a key feature in the success of Community Options. We recognize the effort of the Health Security Act to provide the same flexibility to States and to consumers and we urge you to retain these provisions.

The quality of Community Options is achieved through its highly individualized approach to managing the care of individuals in a manner which respects each person's values and preferences. Cost control is achieved in two ways. First of all, Community Options and the waivers are not an entitlement. A fixed budget is approved

each biennium which finances a number of community care places. Cost control is exercised at the county level where case managers are obliged to maintain an average cost across a case load. There are no individual cost caps. Each case manager is expected to be knowledgeable about the cost of services and about providers and to be a prudent purchaser of service.

Our goal is to achieve a balance between spending on institutional and community care. A second goal has been to expand service options for individuals. Expenditures on personal care, homemakers, home-delivered meals, adult day care, family respite care, housing modification and transportation are emerging as important—as important to keeping people out of nursing homes and functioning at a higher level at home than the historical reliance on skilled nursing care.

A third goal in Wisconsin has been to create a predictable funding source to reduce complexity and to coordinate access to community care.

We hope that Congress recognizes the considerable experience we have developed and the considerable outlay for long-term care already being made by States. It goes without saying that States cannot absorb any new unfunded mandates. We are concerned that this program not become de facto an individual entitlement promising more than can be delivered by the fiscal capacity of either the State or Federal Government.

As a State committed to strong home- and community-based care, we are pleased to have had the opportunity to discuss the program as well as share our concerns. Thank you.

Mr. WAXMAN. Thank you very much, Mr. Born.

[The prepared statement of Mr. Born follows:]

**STATEMENT OF**  
**GERALD A. BORN, ADMINISTRATOR**  
**DIVISION OF COMMUNITY SERVICES**  
**WISCONSIN DEPARTMENT OF HEALTH AND SOCIAL SERVICES**

Mr. Chairman and distinguished members of the House Subcommittee on Health and the Environment, I am Gerald Born representing the Wisconsin Department of Health and Social Services. I am pleased to have the opportunity to talk about Wisconsin's experience in community-based long term care and the proposed long term care portion of the Health Security Act. For more than a decade, states like Wisconsin have been the leaders in developing community-based programs for older persons and other persons with disabilities who choose to receive long term care at home rather than in nursing homes.

There are two reasons we have been in the forefront of long term care reform. First, there is broad support in Wisconsin for public efforts to address the devastating effects of long term chronic illness and disability on the social and economic well-being of families. Governor Thompson has led a significant expansion of home and community-based long term support programs for the elderly and other adults and children who experience chronic physical, mental or developmental disabilities. We are pleased that Congress and the federal administration will be examining the need and the value of a nationwide system of long term care based on consumer choice.

The second reason states like Wisconsin have been the leaders in long term care reform, has been the rising costs of an unmanaged institutional long term care entitlement financed under Title XIX. Governor Thompson and his predecessors have realized that long term care costs will go up, no matter what they do, because of the dramatic rise in the population over age 85, the rising survival rates of adults and children with the most severe disabilities, and the rise in nursing home costs. In spite of this pressure, Wisconsin is required to balance its budget, even as the cost of Medicaid begins to surpass the cost of the University of Wisconsin system. Perhaps most remarkable about our efforts in the long term care field is that it has been a marriage of cost control strategies and the pursuit of improved quality for consumers.

Wisconsin has developed a state-funded Community Options Program, subsequently adding a Medicaid home and community-based waiver, to support in their homes individuals who otherwise would qualify for care in a nursing home. Community Options is administered by county agencies (either social services departments, area agencies on aging or community mental health and developmental disabilities boards) who serve about 13,000 individuals each year. Consumers pay a portion of costs on a sliding scale. Participants receive a comprehensive assessment of their resources and needs from a nurse and social worker, a care plan which reflects consumer preference for types and location of services, and authorization for services from a wide variety of formal and informal providers. Community Options will pay for anything identified in a care plan as necessary to enable the person to remain at home. There is no limiting schedule of benefits or authorized providers, and maximum flexibility and consumer-responsiveness is a key feature in the success of Community Options. We recognize the effort of the Health Security Act to provide the same flexibility to states and to consumers and we urge you to retain these provisions.

The quality of Community Options is achieved through its highly individualized approach to managing the care of individuals in a manner which respects each persons values and preferences.

Cost control is achieved in two ways. First of all, Community Options and the waivers are not an entitlement. A fixed budget is approved each biennium which finances a number of community care "places," just as Medicaid finances a limited number of beds in nursing homes. Cost control is also exercised at the county level, where case managers are obliged to maintain an average cost across a caseload; there are no individual cost



caps. Each care manager is expected to be knowledgeable about the cost of services and about providers and to be a prudent purchaser of services.

Our first goal is to achieve a balance between spending on institutional and community care. We are able now to spend about \$1.00 for the elderly in the community for every \$5.00 we spend in nursing homes. Since a majority of disabled and elderly persons prefer to receive care in the community, we still aim for a better balance in spending in the two sides of the system. Through the last decade, Wisconsin has achieved savings by maintaining a freeze on nursing home expansion while investing in community care.

A second goal has been to expand service options for individuals. Since long term care involves support with basic activities of daily living, it is increasingly clear that traditional home health services and other medical services in and of themselves are not necessary, sufficient or even desirable to meet the daily support needs of participants. Expenditures on personal care, homemakers, home-delivered meals, adult day care, family respite care, housing modification, and transportation are emerging as more important to keeping people out of nursing homes and functioning at a higher level at home than the historical reliance on skilled nursing care. For instance, although it represents less than 5% of expenditures in our program, home modification and adaptive equipment are necessary in 45% of care plans.

A third goal in Wisconsin has been to create a predictable funding source, to reduce complexity and to coordinate access to community care. We would welcome adequate and straightforward participation by the federal government in financing community long term care, unencumbered by excessive regulation or the complexity of the Title XIX waiver administration. Key to the success of state programs like ours has been

the absence of excessive federal intervention in the regulation and definition of programs and services. Where federal Medicaid has been a central funding source, complexity and rigidity inevitably creep in. The nature of the Medicaid entitlement is to breed over-regulation and reduce consumer responsiveness because of the necessity to control cost by limiting service. Fixed budgets as proposed in the Clinton Plan, like our Community Options program, allow for creativity and flexibility within budget caps.

Our state Community Options Program is able to tie money to the individual care plan, to maximize family and community connections and increase consumer choice. In our experience, a participant-centered system of care contrasts with the more traditional programs of Medicare and Medicaid. A participant-centered program leads to new definitions of quality which are more client centered and less dependent on inspection and paperwork.

We hope that Congress recognizes the considerable experience we have developed and the considerable outlay for long term care already being made by states. It goes without saying that states cannot absorb any new unfunded mandates. We are concerned that this program not become de facto, an individual entitlement promising more than can be delivered by the fiscal capacity of either state or federal government. As a state committed to strong home and community based care, we are pleased to have had the opportunity to discuss our program, as well as to share our concerns.

Mr. WAXMAN. Before we go on with the panel, I am going to do something I almost never have done and I hope you will all be understanding. I am sure Ms. Grigsby will be.

Today, we have on the House Floor special legislation because of the earthquake in Los Angeles, which is disrupting the day for me personally, and what I want to do now is recess until 1:30. Then we will come back and pick up the rest of the testimony, then ask this panel questions, and then hear from our remaining witnesses of the day. Ordinarily, as members know, and others who have watched this committee, we usually just keep on going, but we are going to take this break, and I apologize to those of you who might be inconvenienced, but we will recess now and come back at 1:30.

[Whereupon, at 12 noon, the subcommittee recessed, to reconvene 1:30 p.m. this same day.]

#### AFTER RECESS

Mr. WYDEN [presiding]. The subcommittee will come to order, and let me convey Chairman Waxman's regrets that he cannot be here. As you may be aware, the Congress is doing the earthquake legislation on the Floor right now and the chairman's district has been extremely hard hit, so it is a matter of great importance and he will come back just as soon as he can.

Ms. ANSAK, welcome and please proceed. We do have a 5-minute requirement for testimony and we will put your prepared remarks into the record.

#### STATEMENT OF MARIE-LOUISE ANSAK

Ms. ANSAK. Mr. Chairman, I want to thank the committee very much for inviting us here. Today with me is Judy Baskins. She is sitting back there. She is from our replication project in South Carolina and, as you know, in your own district, you have a replication of the PACE project in Portland. Unfortunately, they were not able to be here.

We wanted to take a stand on the security act and look at it from the perspective of the PACE program.

As you know, the PACE program essentially takes care of older people who are nursing-home certified and who need long-term care. We have personally started in San Francisco and we presently have this project replicated with a congressional mandate, which this committee was very active with, and we have it replicated in 12 States. There are a total of 15 projects. All of them are doing well in providing all the health and social services on a capitated basis to those people who are nursing-home certified.

All the projects assume financial risk and provide their services primarily out of day health centers. The services include all medical services, at least from the hospital to the primary care all the way to the portable meal and to transportation.

What we are actually coming here for today is to encourage the committee to help us to expand the program. As you well know, we have at the present time 15 projects through the ORD in HCFA, through the Office of Research and Development. Needless to say, they have been successful.

A study is presently being done by HCFA, but we would like to expand further. There is a lot—there are a lot of requests from var-

ious communities and various States. The States have been very positive about this project and we would like to expand further. Now, ORD, of course, is not able to expand in a limitless way.

We have some concerns about the Clinton bill, and of course also the Cooper bill where it has been mentioned because long-term care is not adequately recognized.

I think the other thing that is a big item in the Clinton bill is that acute and long-term care is not in one package. I think if anything, if anything we have shown in the PACE project why we can be cost-effective is because we are combining the long-term care dollars with the acute care dollars. If you separate those, you are going to push one up and the other one goes down, or vice versa, so we feel strongly that these two should be combined.

I think all in all the PACE project has shown that it is very cost-effective, and in view of this success and the urgent need to replicate further, we would, number one, we would like the committee to help us to broadly expand the availability of the PACE sites ultimately without limitations and defining those sites in terms of the PACE protocol, which we are submitting with our testimony. This gives the guidelines on how a PACE project should be built up and what the quality assurance should be, et cetera.

We would like to facilitate and expedite the development of new sites through a systematic approach that draws upon the experience of the successful PACE sites. Each new PACE site should be complete up to a 3-year trial period before gaining regular provider status. We are actually asking that the bill provide us with some mechanism that after an initial period, these projects could become a regular provider.

If the Clinton proposal were enacted, including PACE as an eligible insurer, in view of its assumption of full responsibility and risk for all health services necessary. PACE should also be authorized as an eligible subcontractor to other insurers or providers where they determine that the frail, long-term patient needs the kind of comprehensive care PACE provides.

Essentially that is—we would like to encourage you to go ahead and to allow us to expand the project.

Mr. WYDEN. Thank you. We will put your prepared remarks in the record and you are absolutely right. We know about the good work that you all are doing in Portland and appreciate it.

[Testimony resumes on p. 380.]

[The prepared statement of Ms. Ansak follows:]



**TESTIMONY**

Marie-Louise Ansak, Founding Executive Director, On Lok, Inc., San Francisco,  
at the Hearings of the Subcommittee on Health and the Environment  
Thursday, January 20, 1994, in Washington, D.C.

Mr. Chairman, Members of the Committee,

I am accompanied today by Judy Baskins, from Palmetto SeniorCare, the PACE replication in Columbia, South Carolina, and Jack Cradock, of East Boston Neighborhood Health Center, the PACE replication in Massachusetts. They are here to assist in answering any questions.

Thank you for this opportunity to comment on the long-term care provisions of the American Health Security Act.

We applaud several features: the focus on community-based services for long-term care, drug benefits, and recognition of the need to integrate acute and long-term care. I will provide more specific comments and suggestions. Let me give you our particular context.

I speak from the perspective of PACE, the Program of All-inclusive Care for the Elderly. PACE is the Congressionally sponsored replication demonstration of the fully integrated, managed care system for the frail elderly that On Lok originated. For 15 years, On Lok has run a highly successful program in San Francisco that meets the complex medical and social needs of the frail elderly. Every PACE enrollee is certified as meeting Medicaid requirements for institutional care.

This model has already been replicated in a variety of communities. In fact, PACE sites are now—or will soon be—operating in 12 states: New York (two sites), Massachusetts, Maryland, South Carolina, Wisconsin (two sites), Michigan, Illinois, Colorado, Texas,

California (three sites), Oregon, and Hawaii. Every PACE site is sponsored by a community-based nonprofit 501(c)3 organization.

The PACE enrollee receives one-stop service, usually based in a day health center. Care is given, usually for life, in all kinds of settings: day health centers, homes, hospitals and nursing home. From the same multidisciplinary team, which includes the primary care physician, the older person gets the quickest possible response as needs change—without the burden and confusion of copayments or deductibles!

Because it assumes financial risk in covering all medical, health and social services, without limit, PACE has built-in incentives to control cost. Its capitation rates, as has been repeatedly demonstrated, save money for Medicare, Medicaid and private payors.

This year 15 PACE sites will serve well over 2,000 very frail elderly persons. A 1993 evaluation by the independent Community Health Accreditation Program (CHAP) showed exceptional quality and coordination of care at all PACE sites reviewed. In addition, the cost savings are about 15%. Hospital and nursing home utilization of PACE participants is much lower than that of the frail elderly not enrolled in PACE.

Many community agencies, providers such as hospitals, and state Medicaid agencies want to establish additional PACE programs. States see PACE as a way to cope with the rapid aging of their population, without building new nursing homes. Others want to apply this model to new groups, such as frail children and persons with AIDS. Unfortunately the present statutory limit of 15 sites is now allocated, making it impossible to meet urgent demand for new sites.

We have four general concerns about the long-term care aspect of the Clinton bill. First, long-term care is not adequately recognized. Gains we have made will be lost. Second, expansion of a successful program such as PACE might be limited to demonstration status in virtual perpetuity under the bill's present provisions. Third, community-based long-

term care ("Title XV") would be segregated from institutional care (Medicaid) and Medicare. This approach promotes categorical funding, fueling the fragmentation and inefficiency we have overcome with the PACE model. Fourth, states are given great flexibility without clear federal guidelines. In implementing PACE, we have seen tremendous variation across states in their sophistication and commitment to long-term care, and even some unfairness. We believe unbridled flexibility might lead to further inequities and confusion for an increasingly mobile elderly population.

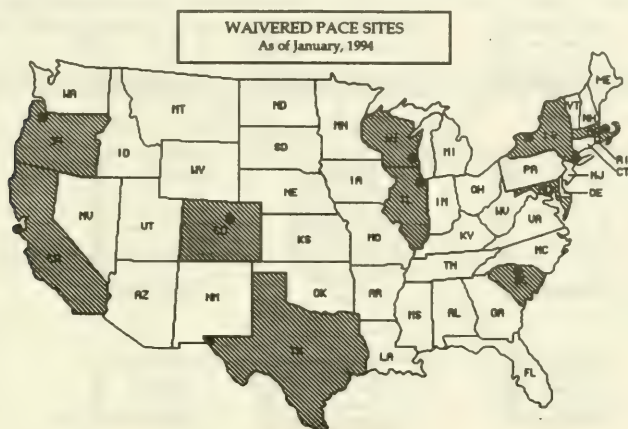
The years of experience with PACE show that it is a proven, cost-efficient way to meet the complex, changeable health care needs of the frail elderly. It is a program urgently needed now and necessary whether you do no more than retain the existing Medicare and Medicaid programs or go all the way up to the Clinton plan.

In view of the PACE replication sites' success and the enthusiastic, urgent interest among community agencies and states in the PACE model, we would like to propose, as an amendment to either existing or prospective law:

1. Broadly expanding the availability of PACE sites, ultimately without numerical limitations, and defining those sites essentially in terms of the PACE Protocol, a draft of which I will submit today. This should be done soon because of the urgent need for new sites and the relatively long lead time for successful development and coordination of the comprehensive services in a PACE plan.
2. Facilitating and expediting the development of new sites through a systematic approach that draws upon the experience of On Lok and the successful PACE sites. Each new PACE site should complete up to a three-year trial period before gaining regular provider status.
3. If the Clinton proposal were enacted, including PACE as an eligible insurer—in view of its assumption of full responsibility and risk for all health services necessary. PACE should also be authorized as an eligible subcontractor to other insurers or providers where they determine that a frail, long-term patient needs the kind of comprehensive care PACE provides.

Thank you. We are also submitting for your information a summary of the PACE evaluation and a listing of the current PACE sites.

The Program of All-inclusive Care for the Elderly—PACE—is a nationwide effort to replicate the comprehensive service and financing model of long-term and acute care created by On Lok in San Francisco. The first PACE replications began operating in 1990. Today, 10 replication sites care for frail older people across the country and five more expect to begin operations by mid-1994. An additional 17 organizations are exploring replication of the model in twelve states and expect to implement the model when additional waivers become available.



**All PACE providers share a common set of principles and must:**

- focus exclusively on frail older persons who are certified eligible for nursing home care;
- maintain PACE enrollees in the community for as long as medically, socially and economically feasible;
- provide comprehensive medical and supportive services through a multidisciplinary team with a broad range of professional and paraprofessional staff, including enrollees' primary care physician; and
- assume financial risk by accepting fixed capitation payments to cover all service needs.

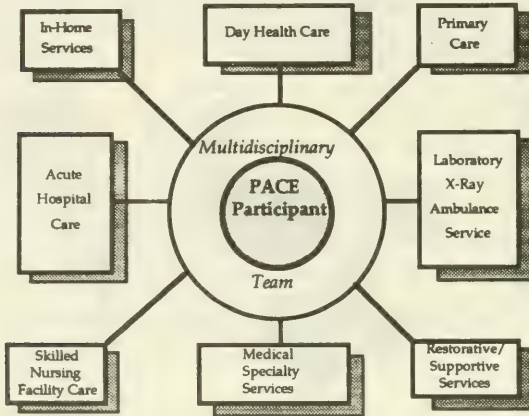


## Service Design

### *Comprehensive Services*

In PACE one organization combines all medical, restorative, social and supportive care. The range of services:

- exceeds traditional Medicare and Medicaid benefits by far;
- extends from hospital and nursing home care to podiatry, dentistry, grooming, transportation and home-delivered meals;
- is available to all PACE enrollees with no limitations on the benefit package; and
- has no copayments or deductibles in addition to the capitation payments.



### *Customization and Prevention*

PACE's multidisciplinary teams develop individualized treatment plans for all PACE enrollees and deliver the majority of services directly. Team members:

- have daily contact with enrollees;
- detect even the most subtle changes in enrollees' conditions; and
- modify enrollees' treatment plans accordingly.

Continuous monitoring and the high level of integration of acute and long-term care services achieved in PACE results in

- dramatic reduction in enrollees' utilization of costly hospital and medical specialty services; and
- preservation of the frail older person's dignity and ability to keep living at home despite severe disability.

### Capitated Financing

By pooling monthly capitation payments from Medicare, Medicaid and private individuals, PACE provides the type, volume, and continuity of services needed, not the often restricted, fragmented benefits package that is available in the traditional system. Capitated financing motivates the programs to keep the frail elderly person functional and ambulatory, which in turn keeps the provider's costs low by reducing the need for high-cost institutional care.

The PACE replication provides a viable community-based alternative to nursing home care:

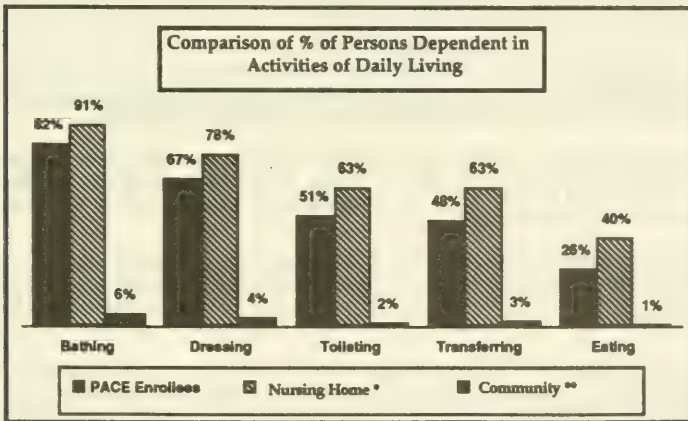
- PACE enrollees mirror a resident nursing home population along a variety of measures;
- PACE's tight integration of acute and long-term care services and emphasis on preventive and supportive services keep enrollees out of institutions, thereby improving their quality of life and reducing costs.

### Success To Date

#### Demographic and Functional Characteristics of PACE Enrollees

Determining who PACE sites are enrolling and comparing the characteristics of clients served with those of other elderly populations are crucial to understanding the impact of the PACE approach.

- PACE enrollees' average age is 78.6; 30% are 85 or older.
- PACE enrollees, on average dependent in 2.8 Activities of Daily Living, look very much like a nursing home population in terms of functional limitations.



\* Source: National Nursing Home Survey

\*\* Source: National Health Interview Summary

- PACE enrollees are dependent in almost all Instrumental Activities of Daily Living (e.g. housework, laundry, managing money, and taking medication as prescribed).
- PACE enrollees have an average of 6.1 medical diagnoses each.
- Like nursing home residents, over half of PACE enrollees are incontinent (PACE: 54%, nursing home: 55%).
- Three-fifths of PACE enrollees are cognitively impaired due to dementing illnesses, including Alzheimer's disease.
- Average length of stay in PACE is about the same as that of chronically ill patients in nursing homes — approximately three years.

#### ***Managing Enrollees' Care in the PACE Model***

PACE providers successfully control enrollees' utilization of high-cost inpatient services by providing expanded preventive and supportive services.

- Despite PACE enrollees' level of frailty, their rate of hospital utilization is just slightly above that for all elderly (2,777 days/1000/annum, vs. 2,845 days/1000/annum, for the Medicare 65-plus population which includes healthy older persons).
- PACE enrollees have shorter hospital stays than the total Medicare 65-plus population (5.4 days vs. 8.7 days).
- Although all PACE enrollees are certified eligible for nursing home care, just 6% actually reside in the nursing home at any given time.

#### ***PACE Cost Savings***

Medicare and Medicaid rate-setting methods for PACE produce savings compared to expenditures in the fee-for-service health care system for equally frail people.

- Medicare's Adjusted Average Per Capita Cost (AAPCC) rate-setting methodology for PACE guarantees Medicare at least 5% savings. In 1993, Medicare monthly capitation rates for PACE ranged from \$619 to \$1,341, reflecting the geographic variation seen in Medicare fee-for-service expenditures.
- Medicaid capitation payments to PACE yield states 5% – 15% savings relative to their fee-for-service expenditures for a nursing-home-certified (NHC) population. In most states, nursing home residents make up the NHC population, but where well-developed home and community-based alternatives exist, those clients costs drive the rate, too.
- An accurate estimate of savings depends upon PACE enrollees and their fee-for-service counterparts being equally frail. A 1993 study by the Long Term Care Data Institute of Medicare's expenditures for a frail, elderly population that was functionally comparable to PACE enrollees found that PACE may actually yield Medicare savings of between 14% and 39%.

- To insure appropriate targeting of PACE services, states verify potential participants' eligibility prior to enrollment. Linking the rate-setting and eligibility determination processes gives states confidence that PACE enrollees match the standard used.
- Beyond the immediate cost savings to Medicare and Medicaid for persons enrolled in PACE, PACE offers states a means of substantially reducing future long-term care expenditures. As the demand for long-term care grows with the size of the 65-plus population, so does pressure to build nursing homes. Starting up PACE costs far less than constructing new nursing home beds.

#### ***Quality of Care in the PACE Model***

Because PACE is a managed care model that enrolls only frail older persons, assuring enrollees' quality of care is extremely important. To augment the quality assurance regulations of the states where PACE providers operate, *Standards of Excellence for the PACE Model* have been developed by PACE and the independent Community Health Accreditation Program (CHAP). To date CHAP has evaluated five PACE sites and found the quality and coordination of enrollee care to be exceptional. All existing and future PACE sites will be evaluated on a regular basis.

#### **Plans to Expand PACE**

The number of PACE providers has grown steadily since 1990 when the first replication sites began enrolling participants. Because the PACE model calls for complete transformation in the approach to caring for older persons with chronic illnesses and severe disabilities, development cannot take place overnight. The level of commitment and financial resources necessary to implement PACE are considerable. To date, programs have taken from three to five years to develop fully. Nonetheless, numerous organizations, including providers in states intent on replicating PACE statewide, seek to operate PACE in the immediate future. Although current legislation limits the total number of PACE replication sites to 15, PACE is currently seeking Congressional authority to expand this number, based on the success of the replication to date.



# **PACE and Potential PACE Sites**

Sponsoring Agency	Program Name	Address	Phone	Contact Person	Status
On Lok, Inc.	On Lok Senior Health Services	1441 Powell Street San Francisco, CA 94133	(415) 989-2578	Kate O'Malley	In Operation
East Boston Neighborhood Health Center	Elder Service Plan	10 Gove Street East Boston, MA 02128	(617) 567-5801	Jack Craddock	In Operation
Community Care Organization, Inc.	Community Care for the Elderly	5228 W. Fond du Lac Avenue	(414) 536-2105	Kirby Shoaf	In Operation
Sisters of Providence-Portland	Providence ElderPlace	4540 NE Glisan Street Portland, OR 97213	(503) 230-6556	Dan Keister	In Operation
Richland Memorial Hospital	Palmetto SeniorCare	2 Richland Medical Park Suite 405 Columbia, SC 29203	(803) 434-3770	Judy Baskins	In Operation
Total Longterm Care, Inc.	Total Longterm Care	3202 W. Colfax Avenue	(303) 573-7230	Linda Barley	In Operation
Rochester General Hospital	Independent Living for Seniors	311 Alexander Street Suite 201 Rochester, NY 14604	(716) 325-1991	Ken Naples	In Operation
Beth Abraham Hospital	Community Care Management	612 Allerton Avenue Bronx, NY 10467	(718) 920-5910	Geri Taylor	In Operation
Bethel New Life	Umoja Care	367 N. Karlov Chicago, IL 60651	(312) 826-5540	Mary Nelson	In Operation
Bienvivir Senior Health Services, Inc.	Bienvivir Senior Health Services	6000 Welch Street Suite A-2 El Paso, TX 79905	(915) 779-2555	Rosemary Castillo	In Operation

Sutter Health	Sutter SeniorCare	7000 Franklin Blvd. Ste 1020 Sacramento, CA 95823	(916) 424-8412	Sandy Smith-Goss	Beginning Operations in 1994
Center for Elders' Independence, Inc.	Center for Elders' Independence	1411 East 31st Street Ward B-2 Oakland, CA 94602	(510) 436-7702	Philip Ayala	Beginning Operations in 1994
State of Hawaii	Maluhia	1027 Hala Drive Honolulu, HI 96817	(808) 845-2951	Audrey Suga- Nakagawa	In Development
Elder Care of Dane County		517 N. Segoe Road Suite 309 Madison, WI 53705	(608) 231-8080	James Kellerman	In Development
Henry Ford Health System		600 Fisher Building Detroit, MI 48202-3012	(313) 874-7205	Linda Lane	In Development
Johns Hopkins Geriatrics Center		Administration Building 4940 Eastern Avenue Baltimore, MD 21224	(410) 550-1118	Christine Nye	In Development*
Sisters of Providence-Seattle		520 Pike Street P.O. Box 11038 Seattle, WA 98111-9038	(206) 464-3355	Chuck Hawley	In Development
Maricopa County Health Care Agency		2121 E. Magnolia Street Phoenix, AZ 85034	(602) 389-4612	Mary Hall Kelly	In Development
St. Joseph's Hospital		3001 W. Dr. Martin Luther King Blvd. P.O. Box 4227 Tampa, FL 33677-4227	(813) 870-4320	David Rogoff	In Development

\* Pending completion of feasibility study.

**PACE and Potential PACE Sites** (Revised 1/14/94)

Christian Church Homes of Kentucky, Inc. / Sanders- Brown Center on Aging	Christian Church Homes of Kentucky The Cumberland Building 12700 Shelbyville Rd., Suite 1000 Louisville, KY 40243- 1596	(502) 244-4200	Robert W. White	In Development
Bethesda Hospital	440 Lafayette Avenue Cincinnati, OH 45220	(513) 861-0400	Richard Fratianna	In Development
CARING, Inc.	407 W. Delilah Road Pleasantville, NJ 08232	(609) 484-8054	Peter Trainor	In Development
Loretto	700 East Brighton Avenue Syracuse, NY 13205	(315) 469-5561	Kathryn H. Ruscitto	In Development
The Eddy	2212 Burdett Avenue Troy, NY 12180	(518) 274-3339	Jonathan Aistrop	In Development
AltaMed Health Services Corporation	500 Citadel Drive Suite 490 Los Angeles, CA 90040	(213) 728-0156	Castulo de la Rocha	In Development
St. Mary Medical Center	1050 Linden Avenue Long Beach, CA 90813	(310) 491-9201	Timothy Holt	In Development
Cherokee Nation	P.O. Box 948 Tahlequah, OK 74465	(918) 456-0671	Gwen Grayson	In Development
Fallon Community Health Plan	Elder Service Plan- Fallon Chestnut Place 10 Chestnut Street Worcester, MA 01608	(508) 835-2550	Molly Zellej	In Development

Lynn Community Health Center/Greater Lynn Senior Services	Elder Service Plan of the North Shore	Greater Lynn Senior Services 8 Silsbee Street Lynn, MA 01901	(617) 599-0110	Vince Lique	In Development
Urban Medical Group	Elder Service Plan-Urban Medical Group	545A Centre Street Jamaica Plain, MA 02130	(617) 522-5464	Rita Chang	In Development
Cambridge City Hospital	Elder Service Plan-Cambridge	1493 Cambridge Street Cambridge, MA 02139	(617) 498-1305	Lori Berry	In Development
Uphams Corner Health Center/ Dimock Community Health Center	Elder Service Plan-Uphams Corner/ Dimock	Uphams Corner Health Center 500 Columbia Road Dorchester, MA 02125	(617) 287-8000	Ed Grimes	In Development
Harbor Health Services/ South Boston Community Health Center/ Manet Community Health Center	Elder Service Plan-Harbor Health Services	Harbor Health Services 398 Eleponset Avenue Dorchester, MA 02122	(617) 282-3200	Daniel Driscoll	In Development



Mr. WYDEN. Mr. Willging, welcome.

### STATEMENT OF PAUL R. WILLGING

Mr. WILLGING. Thank you, Mr. Chairman. It is a pleasure to be with you today to discuss the long-term care provisions of the Health Security Act.

I am Paul Willging, the Executive Director of the American Health Care Association, which represents over 11,000 subacute nursing and assisted living facilities in the country.

We certainly applaud the President and the Health Security Act for being the first of the health reform proposals to deliberately deal with the area of long-term care. We commend you, Mr. Chairman, and this committee, for also being willing to devote as much time to some of the long-term care provisions of health reform as to the acute care side. Certainly, the American Health Care Association supports the principles within the Health Security Act and a good number, if not a majority, of the actual proposals.

The emphasis on the use of nursing facilities in the subacute area, the eligibility refinements within the Medicaid program, the emphasis on long-term care insurance. The recognition of home- and community-based services is a critical part of the long-term care continuum and the mandated medically needy program for nursing facilities services, all critical and important issues to be dealt with within the context of this debate.

We sympathize with you, Mr. Chairman, and your colleagues that as you deal with these very laudable principles, you are inevitably going to have to deal with the fiscal realities. That is going to be a difficult task for you because obviously the issue of dollars will inevitably crop up.

Just to take a few examples. Even the very laudable provisions for Medicaid eligibility enhancement, the movement from \$2,000 up to \$12,000 in terms of retained assets and the movement of the personal needs allowance from \$35 to \$50. Those two together have a half billion dollar price tag.

A very critical part of the President's proposal, perhaps one of the linchpins, which is the mandate that all small businesses and others provide health insurance, will itself in the Federal share of Medicaid alone cost \$700 million per year.

So obviously you have a difficult task ahead of you as you try to combine both the aspects of health reform, which are critical in meeting the needs of the American public and the fiscal realities as to how much one can deal with.

I think this very issue of cost ramifications is absolutely critical in terms of the home- and community-based services proposal. There is no question that we, as all here on this panel, are highly supportive of the recognition finally provided home- and community-based services as a critical part of the long-term care continuum. We do have some questions, however, as to the proposed financing mechanism and eligibility requirements for this program, because they do, inevitably, lead to the issue of cost.

The President has estimated that by the year 2003 the home- and community-based provisions of the Health Security Act would cost \$38.3 billion, and has in fact proposed a cap at that level for this program. A cap might be workable if indeed it was set close

to the actual dollars required to fund the program. Unfortunately, this cap is not so set.

In a study released today, the home- and community-based provisions of the Health Security Act are likely to come much closer to \$69 billion per year by the year 2003 and indeed depending upon one's assumptions could reach as high as \$91 billion per year.

One can talk about a capped entitlement as one does with respect to the home- and community-based services program. In reality, it is a underfunded entitlement, and I think that is the kind of issue the Congress is going to have to grapple with. How does one combine the proposals, the principles, for expanded home- and community-based services with the fiscal realities that are going to have to be dealt with?

I think one option is certainly to look at whether one could incorporate the principles in the programs by the President into a reformed Medicaid program itself. That brings with it, I think, three basic advantages. The first is that by incorporating it somehow within the Medicaid program, we do recognize that those who have the resources to pay for services should in fact pay their fair share, and the scarce Federal and State funding should be reserved for those in fact who have no other options.

Second, by incorporating the program into the Medicaid program, we deal with the issue that we think is a very critical one, the perverse matching proposals that accompany the home- and community-based program. Where the normal Medicaid match is anywhere from 50 percent Federal funding to 78 percent, this one is 78 percent to 95, an incredible inducement for any Medicaid director across the country to make placement decisions based not on the needs of the patient but rather on the needs of the State treasury. An incorporation into the Medicaid program would take away, I think, that perverse incentive.

And finally, I think by incorporating these proposals into ongoing programs such as Medicaid, we have a better opportunity to deal with the very important issues of quality.

The home- and community-based services program is notably absent as far as provisions for quality. You and I, Mr. Chairman, this committee, our staffs, worked in 1987 long hours to make sure that in fact those in need of long-term care, particularly those in nursing facilities, received the protections and the services that the government was paying for.

I am not sure as we worked through those long days and nights, Mr. Chairman, we were trying to protect long-term care patients only in one setting within the continuum. I believe as we talked about adequate staffing, well-trained staff, I believe as we talked about resident assessments and plans of care, I believe as we talked about highest practicable mental, physical, psychosocial well-being, we were talking about all long-term care patients, not just those who happen to be at one spot along the continuum. I think it would be incredibly unfortunate if we were, in fact, to say that the responsibility of Federal and State government, those receiving services paid for by Federal and State government, will receive the protections, will receive the benefits of Federal and State oversight only along a part of the continuum.

In closing, Mr. Chairman, I want to thank you again for the opportunity to talk about these provisions. I want to extend from the American Health Care Association our willingness to work with you as you debate and conclude your discussions in this area.

Mr. WYDEN. Thank you very much. That is very helpful and we look forward to having some questions here in just a moment.

[Testimony resumes on p. 394.]

[The prepared statement and attachment of Mr. Willging follows:]

## TESTIMONY

of the

## AMERICAN HEALTH CARE ASSOCIATION

Paul R. Willging, Ph.D.  
Executive Vice President  
American Health Care Association

Mr. Chairman, members of the subcommittee, my name is Paul R. Willging, Executive Vice President of the American Health Care Association (AHCA), a Washington, D.C. based trade association which represents more than 11,000 nursing and residential care facilities, and the residents they care for, through its 50 state affiliates and the District of Columbia.

I am pleased to appear before the subcommittee today to present AHCA's views on the long-term care provisions of President Clinton's "Health Security Act" (H.R. 3600 and S. 1757). Among the major legislative initiatives proposing to reform our nation's health care delivery system, the Health Security Act enjoys the distinction of being the only proposal to date to seriously begin the debate on reforming the long-term care component of our nation's health care delivery system. By proposing to fund, on a limited basis, home- and community-based services for the disabled, the President has opened the debate on one of the most notable shortcomings of our health care delivery system.

The long-term care provisions of the Health Security Act also include a state option to liberalize eligibility standards for the Medicaid nursing facility benefit, mandatory extension of Medicaid benefits for individuals meeting "medically needy" criteria, a limited skilled nursing benefit as part of the acute care portion of their proposal, and greater regulation of the private, long-term care insurance market (including tax clarifications of the premiums paid for these policies).

Because AHCA testimony presented before this subcommittee in conjunction with the Subcommittee on Commerce, Consumer Protection, and Competitiveness on November 9, 1993 dealt extensively with the subject of increased regulatory standards for private long-term care insurance, my remarks today will focus upon the other long-term care provisions of the President's bill.

#### Overview of AHCA's position on the Health Security Act

The American Health Care Association applauds the President and First Lady for offering comprehensive health care reform legislation -- comprehensive in that it begins to address the need for reforming long-term care services and financing. Like virtually all other organizations with a vested interest in the outcome of the proposal, we support the intent and goal of the



legislation, yet retain reservations on various specific proposals and methods proposed to achieve these mutually agreed upon objectives. It is the purpose of my testimony today to address those specific issues and proposals relating to the long-term care portion of the Health Security Act. I also want to share with you, AHCA's comments, questions, and criticisms so that together, we can achieve the overall goal of the proposal while at the same time, ensure equity for consumers as well as providers in this effort.

#### **Liberalization of Eligibility Standards for Medicaid Nursing Facility Benefit**

Section 4212 of H.R. 3600, "Increased Income and Resource Disregards for Nursing Facility Residents," increases the personal needs allowance for residents of nursing facilities to a minimum of \$50 per month and proposes a state option to allow unmarried individuals applying for nursing home benefits under the Medicaid program to exclude the first \$12,000 of resources. While this proposal, if adopted, would expand access to the Medicaid nursing facility benefit, it would simultaneously have the negative effect of increasing reliance upon the Medicaid program for funding nursing facility services. Clearly, the budgetary goals of health care reform -- reducing overall expenditures and decreasing the reliance upon federal and state funding for services -- presents an inherent conflict with this proposal. While the provider community is not in position to decide the fate of this proposal, we can sympathize with the dilemma facing the policy makers who will ultimately be called upon to make the choice between expanding necessary access to services while striking a balance with fiscally responsible policy decisions.

#### **Extended Care Services**

Section 1119 of the Health Security Act provides for extended care services as part of the acute care benefit established by the bill. In essence, this provision mirrors the current 100-day skilled nursing facility benefit (SNF) under Medicare Part A. This benefit of the Clinton proposal clearly recognizes, as do we, the need for developing and providing for the entire continuum of health care services to beneficiaries.

AHCA believes that the promotion of these extended care services, or "subacute" care, in skilled nursing facilities will generate a substantial financial savings for the health care reform effort. These savings will come from utilizing the more efficient, free standing SNF providers who have developed efficiencies that do not exist in hospital-based post acute services. In addition, Medicare routine cost limits for hospital-based SNFs are higher than those for a free-standing SNF. Because both hospital-based and free-standing SNFs provide identical services, the establishment of a shared routine cost limit will generate additional savings to the government. The

similarity in services between these two delivery sites results primarily from a continually escalating acuity level of nursing facility residents over time which has compelled the free-standing SNF provider community to adjust its services accordingly. The President's proposal has recognized this phenomenon, and on September 29, 1993, in her testimony before the Senate Labor and Human Resources Committee, the First Lady stated, "...we want to provide reimbursement for subacute care at nursing facilities rather than in a more expensive hospital setting."

For a more detailed discussion of the role of SNFs in providing subacute care services under the Health Security Act, I would refer the subcommittee to my testimony submitted to the Ways and Means Subcommittee on Health on November 2, 1993.

#### **Home- and Community-based Care Services**

Possibly the most ambitious of the Health Security Act's provisions, the President has proposed the creation of a new "capped" entitlement program to provide home- and community-based services (HCBS) for individuals with disabilities. AHCA supports the development of public assistance for these services, and considers this provision of the HSA to be a good beginning for the subsequent discussion of proposals to develop the infrastructure it will take to properly implement it. However, AHCA has several questions and reservations about how the benefit is to be implemented and operated.

#### State Plans

As proposed, the HCBS program would be an optional program for states, whose participation would depend upon federal approval of a state plan meeting specified requirements such as: eligibility requirements, provider participation requirements, reimbursement standards, and how federal funds are utilized to meet the objectives of the program. It is anticipated that the state plan submission and approval process would be very similar to the current Medicaid participation approval process currently in place. AHCA shares with the Administration, its interest in extending to the individual states, flexibility in designing their own delivery system reflecting the unique characteristics and needs of the communities which will be served. AHCA and its membership have an extensive history dealing with all 51 Medicaid programs as well as with the federal regulators overseeing these programs. Our collective experience has taught us that state plans, and their subsequent approval for programs such as this are not a guarantee of compliance. This subcommittee is well aware of the laws it has been forced to enact to require state's to amend their Medicaid plans in order to conform with new or modified federal requirements of participation. The states, facing limited Medicaid budgets have not been as eager to sufficiently fund the expansion of quality, services, and access to care that their federal counterparts have imposed upon them.

Although the home- and community-based program contained in the Health Security Act is not part of the Medicaid program, the cap imposed on the federal revenues available to fund the costs of care create similar restraints on the availability of services. AHCA supports strengthening the federal oversight of the state plan approval process and urges this body to specify the criteria under which state plans are approved.

#### Eligibility Requirements

As introduced, federal and state funding for the home- and community-based services program would be available to individuals with disabilities without regard to income, age, residential setting, and other criteria apparently designed to ensure universal access for disabled individuals. While this represents a laudible goal, we feel that the capped nature of the funding for these services prohibits states from being able to meet all of the needs of their entire disabled population. We believe that the individual states will be compelled to establish beneficiary selection criteria due to the limited funding available for providing services. In spite of the fact that the bill prohibits state plans from allocating services based upon income, we believe that such a "means test" is an appropriate manner to determine program eligibility in light of the limited funding provided for in the proposal.

#### Quality Assurance and Safeguards

As part of the state plan, it must specify how the state will ensure the quality of services delivered through the home- and community-based program. We are discouraged by the plan's deference to state regulatory authorities to establish this critical feature of the proposal. The long-term care provider community cannot endorse any proposal that does not include a specific and thorough set of standards from which the safety and well-being of beneficiaries can be ensured. Compounding this problem of the proposal is the lack of any provision which would require periodic surveys or evaluations of provider services and qualifications. While state plans must provide for the "monitoring" of services, no comprehensive evaluation of the quality of care is provided for in the legislation. In its simplest terms, this program will permit individuals into the residences of the elderly or disabled, with no specified professional qualifications while unsupervised. The potential for crimes and abuse against the beneficiary is too great for Congress to ignore. AHCA recommends that federal standards for caregivers be created and that federal oversight, including oversight for a comprehensive survey system is included in the proposal.

#### Home Care vs. Institutional Care

Aside from the genuine need to include home- and community-based services as part of health care reform, there is reason to

believe that the HSA's authors intend to realize savings by diverting individuals needing institutional long-term care to home- and community-based programs. This belief stems from the misconception that nursing facilities/care for ambulatory residents who, except for assistance with certain activities of daily living, could just as well continue to reside in the community with minimal assistance. A profile of the needs of the nursing home population shows that a full 69 per cent require assistance with four or more ADLs (Lewin-VHI Inc., 1993). Considering the limited funding of the HCBS program and distinct lack of professional qualifications imposed upon caregivers under the program, it is unlikely that meeting the same level of need as determined by the Lewin-VHI Inc. study was anticipated by the bill's authors. Institutional long-term care providers do not view the establishment of a home- and community-based care benefit as competition. If for any reason at all, our nation's demographics indicate that there will be more individuals seeking long-term care services than there will be financial resources to care for their needs. But we must not delude ourselves into believing that home- and community-based care provided by unlicensed individuals in an unsupervised environment is a panacea for states who cannot afford to pay for the institutional long-term care needs of their frail elderly population.

It is a fact that nursing facilities care for a separate and distinct population than those served by home care. The distinctions between these two populations is addressed in the AHCA Issue Brief, "Home Care and Nursing Home Care: Serving Separate Populations" which I have attached to this testimony.

#### Financing Home- and Community-Based Services

Although it has been estimated that the \$65 billion commitment made by the HSA will serve the needs of approximately one-third of the disabled population, the minimum 78 per cent federal match (and up to a maximum of 95 per cent) sets new standards of generosity for health care programs jointly funded by the federal and state governments. While this may induce the states, who may otherwise be reluctant to increase the level of services available to the disabled to participate in the program, it also creates a perverse incentive to make placement decisions based upon financing grounds, rather than the actual level of care needed by the beneficiary. Specifically, a state Medicaid program with a 50 per cent federal matching rate is required to pay one-half of the costs associated with extending the Medicaid nursing facility benefit to every resident admitted. Conversely, diverting that same potential resident to a home- and community-based care program would cost the state a maximum of 22 per cent of the costs of care; clearly generating a financial savings to the state, while increasing access to more beneficiaries. Therefore, monies could be shifted from the state Medicaid program that pays for nursing facility care and used to enhance the ability to increase the federal revenues made available for home- and community-based services. We recognize that the



"capped" nature of the home- and community-based services program would place an overall limit on this ability to generate additional federal dollars for use by the states. However, even Congress' own Congressional Research Service pointed out that, "While funding for the program is substantial, there are concerns that it may nevertheless arouse expectations it cannot satisfy. ... Over time, there might be pressure to convert the program from a fixed block grant to an entitlement." (CRS Report for Congress. Health Care Reform: President Clinton's Health Security Act, p. 66, November 22, 1993). Given the diverse nature of the constituency a program such as this could generate, CRS' predictions are not unrealistic. If these predictions were to become a reality, the financial implications for meeting consumer expectations to both the federal as well as the state governments would be substantial. AHCA urges Congress to include safeguards into this proposal to ensure that individuals are placed within the appropriate delivery setting for the care they need and that the funding for institutional long-term care services not be diluted to enhance alternative delivery mechanisms.

#### Restrictions on Delivery Sites

Section 2104 of the Health Security Act would prohibit coverage of home- and community-based services furnished in a nursing facility or intermediate care facility for the mentally retarded. While this provision is consistent with the intent of making non-institutional long-term care services available to beneficiaries, AHCA requests that this provision be clarified. Specifically, we request that existing institutional long-term care providers not be precluded from offering home- and community-based care services in conjunction with other institutional services. For example, "residential care" sites provide for living arrangements offering minimal assistance with activities of daily living while at the same time and within the same physical environment, offering other beneficiaries services that extend through the entire long-term care continuum up to and including skilled nursing care. These arrangements have proven popular with beneficiaries primarily because the need for institutionalization does not necessarily mean displacement from other residents, loved ones, or spouses. By promoting the integration of the entire spectrum of long-term care services, beneficiaries are able to retain their sense of community and continuity. AHCA believes that this is a positive development in the long-term care delivery system and one that Congress and this subcommittee should promote.

#### Conclusions

When the long-term care provisions of the Health Security Act are looked upon for their intent to increase services, they are laudable; however, much, much more needs to be done in this area of our health care delivery system. In addition to funding the costs of services, additional revenues will be needed in

order to create the infrastructure necessary to ensure both quality of care and availability of services. Adequate funding for all long-term care services needs to be guaranteed. The home- and community-based program proposed by President Clinton will not replace the need for institutional long-term care. We strongly encourage the maintenance of a separate and distinct funding source for these services.

As an exercise in constraining the budgetary pressures that have generated this debate, we are concerned that inadequate funding will be made available to finance new long-term care programs. The majority of funding for the home- and community-based services program comes from Medicare and Medicaid budget cuts that do not enjoy much popular or political support. Without adequate funding, this important new program could end up a hollow promise to the thousands of individuals it hopes to help. Reconciling policy aspirations with budget realities will undoubtedly remain the most difficult aspect of health care reform.

Thank you for this opportunity to testify and to present the views of the American Health Care Association. If you have any questions, I'd be pleased to answer them at this time. Thank you.

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# ISSUE BRIEF

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American Health Care Association

## HOME CARE & NURSING HOME CARE: SERVING SEPARATE POPULATIONS

As the 76 million Americans born during the Baby Boom years grow older, the search for attractive alternatives to nursing home care gains intensity. Over the years, home and community-based care (HCB) programs have become increasingly popular with lawmakers, the media, and the public.

Government spending reflects this widespread longing for HCB care. From 1980 to 1990, Medicaid spending on HCB programs increased from \$300 million to \$2.2 billion, according to the Health Care Financing Administration (HCFA). Today, all states offer HCB programs; the District of Columbia does not.

Supporters justify the need for HCB care by asserting that it is a cost-efficient *alternative* to nursing homes. While public sentiment for HCB care is high, three myths about nursing facilities and the people who live in them perpetuate the misperception that HCB care is a cost-effective substitute for nursing home care.

### MYTH #1: Nursing Home Residents Generally Can Care For Themselves With Minimal Assistance.

Most of the public erroneously assumes that nursing homes provide custodial care for older, generally ambulatory people. But the typical nursing home resident is older and needier than a decade ago.

According to the U.S. Census Bureau, 22 percent of Americans age 85 and older live in nursing facilities. In 1960, only 5.6 percent of Americans were 85 and older. That figure skyrocketed to 10.3 percent in 1990. (1)

Octogenarians, of course, suffer more chronic and serious medical problems than the "young" elderly. But no matter how old, a typical nursing facility resident simply is unable to live independently — even with daily visits from a health care professional.

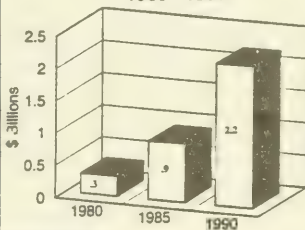
A full 69 percent of nursing facility residents age 65 and older need help with four or more activities of daily living (ADLs), which include transferring, toileting, feeding, bathing and dressing, and mobility. This compares to only 21 percent of the general elderly population. (2)

Nursing facilities, no longer the custodians of yesterday, have adjusted to meet this demand for complex medical services.

More and more nursing homes — already equipped to handle serious medical needs that cannot be accommodated in a home setting — are beginning to specialize. They are offering, for example, special AIDS, Alzheimer's, and rehabilitation units.

Nursing facilities also are moving rapidly into the "subacute" market, providing services for people who need skilled care, but do not require the expensive, acute-care services of a hospital. Examples of subacute services include intravenous therapy, complex wound management, and rehabilitation for stroke patients.

**Growth in Medicaid HCB Spending  
1980 - 1990**



Source: Health Care Financing  
Administration, HCFA

Bruce Vladeck, head of HCFA, has recognized the importance of nursing facility care to the elderly American.

Vladeck wrote in a 1989 article: "... there is little question that in most communities, most nursing home residents are pretty ill and pretty disabled. Almost all have multiple, serious medical problems; perhaps as many as half have significant cognitive impairments.

"Continuing growth in the number of impaired elderly persons necessitates a continued reliance on nursing homes to care for at least those who are most impaired or most lacking in other supports ..." (3)

### ADL Dependency in Nursing Home Residents and General Elderly

#### Nursing Home Residents



#### General Elderly



\*Dependent in four or more ADLs

Source: Lewin-VHI Inc., June 1993

### MYTH #2: Home And Community-Based Care Will Reduce Nursing Home Utilization

The services offered in nursing homes and the services provided by HCB care simply cannot be compared.

Study after study — spanning more than a decade — has shown that substituting HCB care for nursing home care is unrealistic because separate populations utilize each service.

Consider the following:

\* **General Accounting Office (1987):** "HCFA now assumes that all those receiving home and community-based care otherwise would use nursing homes ... HHS funded research and demonstration projects do not support this assumption. Many

people who have participated in community care demonstration projects would not have entered a nursing home had the community-based care been unavailable." (4)

\* **General Accounting Office (1982):** "When compared to an elderly population for whom traditionally available care is offered, recipients of expanded community-based services do not use significantly fewer days of nursing home care." (5)

### MYTH #3: Home And Community-Based Care Will Reduce The Total Cost Of Long Term Care.

Several studies that explore whether HCB care can be a viable and cost-effective substitute for nursing home care reveal that HCB care actually *increases* the total costs of long term care.

HCB care is a "new service directed at a new population," explains William Weissert, former director of the Program on Aging at the University of North Carolina. (6) Consequently, communities that offer HCB programs spend more resources on long term care than do communities without HCB services.

Over the years, study after study has proven that HCB care does not reduce the costs of nursing home care:

\* **Institute for Health Policy (1993):** "Increased financing for HCB services may be desirable but will not significantly influence nursing home expenditures. The underlying assumption is that the delivery system is correct, but funding is inadequate. ... We must seek to justify HCB on grounds other than cost effectiveness or clinical efficacy: the debate should focus on how much community care we are willing to purchase as a society, rather than how much money we can save by purchasing these services." (7)

\* **The Brookings Review (1990):** "Given a choice between nursing home care and nothing, many elderly people will choose nothing. But when the choice is expanded to include home care, many will choose home care. Thus, the costs associated with large increases in home care more than offset small reductions in nursing home use." (8)



\* **Health Services Research (1988):** "The overall conclusion that the demonstration services led to increases in average costs is quite certain." (9)

\* **Health Services Research (1988):** "The increased costs of case management and expanded community services exceeded the cost savings from reduced nursing home costs." This study concluded that overall long term care costs associated with adding a HCB care benefit increased between 6 and 18 percent. (10)

\* **General Accounting Office (1987):** "For the majority of ... clients receiving home and community-based services under the project, these services represented added costs for a new Medicaid benefit rather than a cost-effective substitute for nursing home care." (11)

## CONCLUSION:

More than a decade of government studies, pilot projects, and demonstration programs have exposed the fallacy of assumptions that: a) nursing home residents generally can care for themselves with minimal assistance; b) HCB care will reduce nursing home utilization; and, c) HCB care will reduce the total cost of long term care.

It is a time-tested fact that nursing home residents generally cannot live on their own. It is a time-tested fact that HCB care and nursing homes serve different populations. It is a time-tested fact that HCB care does not reduce the cost of long term care; it actually increases the amount spent on those services.

The myths about the intersection of HCB care and nursing homes persist because the public has expressed a strong and understandable desire to receive care in the most comfortable and familiar setting possible.

But that sentiment cannot mask the reality. Many jurisdictions are beginning to confront the myths used to justify HCB care. Witness, as reported in the *Reimbursement Bulletin*, the recent problems in New York, which consumes a full 63 percent of all Medicaid dollars spent on home care:

"Panicked by forecasted increases in the elderly population, New York wants to scale back on home

care — the fastest growing item on the state's \$13.9 billion Medicaid tab. The New York Department of Social Services reports that annual costs for home care have doubled in the past four years to \$2.4 billion. While Medicaid officials still see home care as cost-effective, they are also admitting that it can be more expensive than nursing facility care in some cases. This is especially true when it is used as a primary care service rather than a supportive service." (12)

The American Health Care Association (AHCA) believes that while the need for nursing home services will grow, HCB programs are a vital part of what long term care can offer.

Appropriate care in the appropriate setting is in the common interest of all providers — providers of HCB care and providers of nursing home care — as well as of those needing long term care.

# SOURCES:

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(4) United States General Accounting Office. "Medicaid: Determining the Cost-Effectiveness of Home and Community-Based Services." April 1987; 3.

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(6) Weissert, William. "Seven Reasons Why It Is So Difficult To Make Community Based Long Term Care Effective." Health Services Research October 1985; 20 (4).

(7) Hallfors, Diane Dion. Center for Vulnerable Populations, Institute for Health Policy, Brandeis University. "State Policy Issues in Long-Term Care for Frail Elders." March 30, 1993; 8.

(8) Wiener, Joshua M. and Katherine M. Harris. "Myths and Realities: Why Most of What Everybody Knows About Long-Term Care is Wrong." The Brookings Review Fall 1990; 32.

(9) Thornton, Craig and Shari Miller Dunstan and Peter Kemper. "The Evaluation of National Long Term Care Demonstration: 7. The Effect of Channeling on Health and Long Term Care Costs." Health Services Research April 1988; 23(1): 130.

(10) Ibid., 141.

(11) "Medicaid: Determining the Costs....18.

(12) "New York Officials Sound Alarm Over Bureaucratic Home Care Bill." Reimbursement Bulletin February 16, 1993; 5 (17): 6.

Mr. WYDEN. Mr. Goldberg, welcome.

# STATEMENT OF SHELDON L. GOLDBERG

Mr. GOLDBERG. Mr. Chairman, thank you very much. It is my privilege to appear before this committee. It is a committee which has for a long time provided leadership and has championed the issues of access to the poor, and proper health care services and quality.

My name is Sheldon Goldberg. I am the President of the American Association of Homes for the Aging. I think I come here today from a unique perspective. Yes, my members are all not for profit. There are 5,000 across this country. Today almost a million people receive services. We represent nursing homes, but equally we represent housing, community services, retirement communities, low-income housing, a broad range of other types of services.

I have to tell you something, I am excited at being here with the opportunity it presents. First of all, there is so much within the President's proposal which we support. Number one is the public-private partnership, the ability to infuse dollars into the program from those who have those resources. Most importantly, it is support of the home- and community-based services program. We see this especially for those who reside in the housing program, low-income housing 202 as an opportunity to provide appropriate services to keep them independent as long as possible.

We support the provisions which are involved pertaining to the expansion of long-term care as well as providing consumer protection by bringing a standard of, Federal standard to minimally regulate these to make sure it is appropriate for the consumers across this country.

Demographically, we are at a crossroads in this country, and I hope that the Congress can seize the opportunity or seize the moment to move forward with long-term care reform.

I recognize the fiscal realities we face, but it is my hope that the Congress will not jettison these issues and move on to health care reform without addressing this critical issue. Our fear is if they are not addressed now, it may be years in the future before we again talk about them.

We are concerned, obviously, about the fiscal nature. We feel and strongly support the idea that the costs of the community base have to be on a sliding scale basis. To those who have the least amount of money to pay for them, they are the ones who should be receiving these services for free, and it needs to be directed in that way, and those who can afford to pay for the services, obviously they are the ones who should pay for them.

We support this on the same premise that we feel there is probably going to be, to some degree, an adverse effect on nursing home payments. Certainly the freeze on Medicaid, Medicare, will have an impact. Because these are the sickest and the residents with the most promise of rehabilitation.

We had hoped that the freeze could be lifted. We see more and more Medicaid residents coming into the nursing homes in the future simply by the demographic nature of what is going on. Our hope is we will not see States reallocate funds from the Medicaid program to provide proper reimbursement and to support other

types of programs. We hope there is a commitment to maintaining the principles advocated for in OBRA 1987.

Now, let me add a very major concern. There is a recent Federal court decision in New Jersey that defined in the 1987 OBRA, which this committee helped to write and champion, the highest practical level for the well-being of the resident. This court said, number one, that we will not support a superior standard of care. It said, number two, we will not support excellent care. And what concerns me the most is the court's ruling said it will not, quote, "support compassionate care." And I think what you have worked for for so long, and this is that we do not have a double-tiered system of care and that we have one system of care that is responsible to all, and that is why we are advocating that we do have safeguards to maintain a quality level and reimburse them for the care side of it.

There is another provision that causes concern, and that is the idea that a new model exists called continuing care retirement communities, which is starting up, would possibly require that there is a minimum standard Federal regulations related to the Federal Government. CCRC's in this country are really very locally community-based organizations most of them sponsored by churches at the community level. I find it very difficult for them having the ability to relate to a Federal bureaucracy. We believe very strongly that they are really State issues. There are proper roles for the regulation and safety.

We also advocate that there are an existence of accreditation programs, which are consumer driven, resident driven, that we think could adequately address those issues as well, and let me be very quick and come to a conclusion.

We support very wholeheartedly the home- and community-based system. We support the concept that it be on a sliding scale so the economic resources that are there go to those who are the most poor and who need those resources. I will suggest very strongly that they have to be available for people in their residences. I use programs such as the 202 and other low-income housing programs. We obviously are very supportive of the provisions in OBRA 1987, at the highest level practical be maintained and not diminish in terms of those who reside in nursing homes. We see minimum Federal standards for long-term care insurance. They are needed; it is proper so we don't have a hodgepodge confusion in terms of how we approach and regulate insurance in this country. It needs one standard. We support CCRC's and obviously we oppose the freeze on Medicare. I appreciate your leadership and your opportunity for allowing me the opportunity to speak. Thank you very much.

Mr. WYDEN. Thank you very much, Mr. Goldberg. That is very helpful.

[The statement of Mr. Goldberg follows:]





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Mr. Chairman, I am pleased to be here today to testify on the critical issue of health care reform. I am pleased that this issue is a top priority on both the President's and Congress' domestic agendas and AAHA stands ready to lend our organization's assistance in helping draft a solution to insure adequate access to quality health and related services and financial protection for these services.

AAHA is a national organization representing almost 4,500 non-profit providers of health care, housing, and community-based services for the elderly. Our members provide not only nursing facility care, but also independent senior housing, assisted living services, continuing care retirement care, home health care, adult day care, respite care, meals on wheels, and others services in a continuum of care to enable elderly individuals to remain independent as long as possible, as well as to care for them when they can no longer care for themselves. AAHA is committed to the reform of our nation's long-term care system as an integral part of health care reform. Only through such reform can we assure our nation's 32 million elderly citizens access to needed long-term care services and adequate funding for such care. Representing providers who collectively offer the full range of aging-related services, the Association recognizes the value of an array of housing and health-related services to ensure that the chronically-impaired elderly receive appropriate and cost-effective care in the most appropriate setting that accommodates their individual needs and circumstances.

I want to applaud you, Mr. Chairman, for your leadership role in assuring high quality long-term care services for those who need them. Many of the dramatic improvements in nursing home quality - in resident assessments, reduction of physical and chemical restraints, and residents rights - are the result of this Subcommittee and its staff. Today you are continuing your efforts to ensure that long-term care remains a vital component of the health care reform movement.

The needs of our elderly citizens must not be overlooked. Roughly 32 million older Americans are without protection against the potentially catastrophic costs of long-term care services. The average cost of nursing home is approximately \$36,000 annually. While lower than nursing home costs in some cases, home care costs for an individual receiving three visits per week would range between \$10,000 and \$15,000 per year, depending on the type of services and providers involved. Few elderly individuals can afford to pay for these services themselves, so they are forced to impoverish themselves to qualify for Medicaid. There must be a better way; that is one area in which we all agree.

President Clinton has begun to improve long-term care coverage and financing with his Health Security Act. That plan would create a sweeping new home and community-based care benefit that would benefit all disabled individuals regardless of age, income, geography, nature of disability or

*Representing not for profit organizations dedicated to providing quality health care, housing and services to the nation's elderly*

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residential setting. A wide range of services could be provided under the program, thus enabling many individuals to remain as independent as possible. The President's proposal would also include in the basic benefit package an "extended care" benefit to cover 100 days of nursing facility or rehabilitation facility services as an alternative to hospitalization after an acute illness or injury. The plan would be based on joint public and private efforts to cover long-term care services.

There is much about Clinton's plan with which we agree:

- We agree that a new long-term care benefit must be based on a public and private partnership, with critical roles for both the government, the individuals, and insurance. A partnership is essential in order to finance needed services in light of budget constraints. A partnership can also result in more innovative financing and delivery models that accommodate the unique needs of special populations, promote quality assurance, and provide services in a cost-effective manner.
- We agree with the need for expanded home and community-based services, provided in homes or residential settings, to promote independence. Such programs recognize that most frail elderly individuals would prefer to be served in their own homes, whether those are private residences or congregate residential settings.
- We agree with the need for state flexibility to create long-term care service packages that best meet the need of their citizens.
- We agree with the need for federal incentives for long-term care insurance, to encourage those who can pay for their own care to do so.
- We agree with the need to regulate long-term care insurance to protect consumers.
- We agree with increasing the Medicaid personal needs allowance for individuals in nursing facilities to \$50.00, as a modest investment in an improved quality of life for indigent residents.
- We agree with the need to increase the amount of assets that may be protected, so that eligibility for Medicaid does not require the dire impoverishment it now does.
- We agree with the creation of an extended care benefit as part of the basic benefit package. We support that proposed benefit, as we believe that nursing facilities are a cost-effective setting in which to provide subacute care.

I want to emphasize a couple of those areas of agreement.

The centerpiece of the President's long-term care package is an expansive

home and community-based care benefit, which could provide a broad array of services to disabled individuals of all ages. To AAHA, one of the most important parts of the proposal is the availability of services in all settings ranging from one's individual home to congregate residential care settings, such as senior living or assisted living facilities. The President's plan provides an important new opportunity to knit together health and housing benefits in ways to assist thousands of low-income, elderly Americans lead a healthier and more independent life. The home and community-based care benefit can complement other forms of programs such as HUD rental subsidies, Supplemental Security Income, etc.

AAHA strongly believes that federal and state housing assistance have a direct bearing on health status and well-being among the elderly. For example, a recent survey by one of our members showed that residents receiving federal housing assistance were able to finance their own Medigap policies and prescription drugs. Without such rental assistance, many of these individuals would be forced into public assistance programs to finance needed health benefits.

Other examples of the benefits of assisted living abound. With the supportive services available through the federal Congregate Housing Services program, for example, older persons in 60 sites across the country are saving the federal government an average of \$5,000 per person annually. AAHA applauds the Administration for allowing home care services to be delivered in a variety of settings, thus fostering this important link between housing and supporting community services.

We do have concerns about the President's proposal however.

I will be candid with you, Mr. Chairman. A broad (and expensive) home care component that is perceived as a new entitlement could jeopardize any new long-term care coverage. Many members of Congress and Congressional staff to whom we speak are talking about abandoning the long-term care program in order to save money for the basic health care reform package. While we believe that the home care benefit proposed by the President has merit, we are pragmatic enough to believe that it must be limited in order to secure enactment.

I would like to point out that while we do support expanded home care services, home care is not always less costly than institutional care, particularly for individuals who have serious deficits in activities of daily living. Even Bruce Vladeck, Administrator of the Health Care Financing Administration, recently noted a concern about the misconception that home care is always less expensive than care in an institutional setting.

A further concern relates to the adverse impacts we believe the Clinton health care reform plan would have on nursing facilities. The President's plan would perpetuate the effects of the current freeze on Medicare skilled nursing facility cost limits, resulting in reduced Medicare reimbursement for facilities. It is unclear to what extent the new extended care benefit

in the basic health care package would provide additional revenues for nursing facilities. The new home care benefit would likely result in some residents being relocated to other settings, thus shifting funds away from nursing home services into home care. While this may be appropriate in some instances, OBRA 1987 provided a process whereby all nursing facility residents are screened before entering the facility to ensure that nursing facility placement is appropriate. Under that process, few current residents would be seem eligible to be transferred. But we are concerned that states may seek to maximize federal dollars by availing themselves of the enhanced matching rate under the new home care program, and may transfer residents notwithstanding the appropriateness of the current placement. Make no mistake: the level of frailty and infirmity in nursing facility residents is increasing.

We are also concerned that, as a result of the new home care benefit, greater numbers of individuals entering nursing facilities will be more frail and Medicaid-eligible, having spent much of their savings to remain in their homes or in assisted living settings longer. Furthermore, because states will have to continue to pay for Medicaid-eligible nursing facility residents who are not transferred, but will still have to find new dollars to fund the new home care benefit, states may seek to reduce nursing facility rates even further. The President's plan does not include any changes to remedy current problems with Medicaid underpayments for the costs of care. In short, more nursing facility residents will be on Medicaid, there will be fewer private pay residents to subsidize low Medicaid rates, and the Medicaid payment base of nursing facilities is likely to erode even more substantially.

This problem of inadequate Medicaid rates is exacerbated by the potential undermining of important nursing home reform provisions in a recent court case. OBRA 1987 required that nursing facilities must provide services to their residents to meet the "highest practicable physical, mental, and psychosocial well-being" of residents. Thanks to this Subcommittee, OBRA 1990 clarified that the Boren amendment (which requires adequate rates for efficient and effective nursing facilities) requires states to consider the costs of meeting the "highest practicable" requirement in determining their Medicaid rates. In New Jersey Association of Health Care Facilities, Inc., et. al. v. Gibbs, et. al., No 90-1908 (D. N.J., March 4, 1993) the court ruled that the "highest practicable..." language of OBRA 90 was intended to reduce Medicaid expenditures, rather than to require increased payment when increased costs were incurred to provide highest practicable services. The court also interpreted a "practicable" level of care as one that represents a balance between the statutory objective of cost containment and other nursing facility requirements. The court opined that federal law does not require Medicaid beneficiaries to receive a "superior standard of care," "excellent" care, or even "compassionate care". Rather, the court viewed these as luxuries which may be "permissible, even laudable goals" for attracting "more private pay residents", but are clearly above and beyond the level of service Congress envisioned funding through Medicaid. AAHA fears that this decision can be interpreted as meaning that "highest practicable" requirement in OBRA now means however much quality



the state "can afford" or is willing to fund.

This decision conflicts with the OBRA 1987 requirement that nursing facilities must maintain identical policies and practices regarding the provision of services required under the state Medicaid plan for all residents, regardless of payor source, and gives nursing facilities a Hobson's choice. Either facilities may seek to maintain two levels of care (one for Medicaid beneficiaries and one for private pay residents) as the Third Circuit seems to endorse, in violation of OBRA 1987, or facilities could be forced to reduce staffing levels, as they seek to conform to only the state minimums for which they will be paid. The Third Circuit's "least common denominator" approach (or "it's good enough for Medicaid residents") seems totally at odds with the concept of "highest practicable well-being" that lies at the heart of OBRA's nursing home reform provisions.

Mr. Chairman, we are aware of the financial problems many states have been having in recent years. But those problems do not lessen the need for nursing facilities to receive adequate payments to support quality services. We strongly urge you to include enhanced Medicaid payment protections in your mark-up of the health reform bill, in order to preserve the hard-won improvements in resident standards and care of OBRA 1987, and to ensure the availability of nursing facility beds for those who need them. We particularly ask your assistance in clarifying the "highest practicable" requirement and the obligation of states to pay for services to meet that requirement.

The President's proposal could also stifle a creative approach to financing, managing and providing long-term care which is provided by continuing care retirement communities (CCRCs). The bill would contemplate regulating CCRCs under federal long-term care insurance standards, a move AAHA opposes. Inclusion of CCRCs in the proposed long-term care insurance standards would undermine the actuarial soundness of CCRCs by prohibiting them from looking back further than six months into pre-existing conditions of potential residents, or from basing eligibility on the type of service, level of care or type of provider needed. These prohibitions would not only undermine the financial stability of CCRCs, they would also eliminate the ability of CCRCs to effectively manage the care of their residents. While CCRCs are not now a large proportion of long-term care providers in this country, they are a creative alternative for many older Americans that minimizes the need for federal funding for long-term care services. The CCRC option should be promoted, not inhibited. In the event that Congress feels the need for any additional quality monitoring beyond current state regulation, we urge you to rely on accreditation to meet that need. The Continuing Care Accreditation Commission has been accrediting CCRCs for eight years. The Commission maintains strong consumer participation through membership in its board of directors, and the Commission is rapidly gaining acceptance among consumers as the quality seal of approval for retirement communities.

Mr. Chairman, we want health reform enacted, and we want long-term care

included in the health reform package. If long-term care is not included as part of health care reform, we fear that it will be another thirty years before Congress returns to the issue.

To be enacted, we feel that the long-term care benefit in the Clinton proposal needs to be scaled back somewhat, and to be better balanced in terms of covering both home care and nursing home services.

Our Public Policy Committee is deliberating today, even as we speak, and we would like to provide more specific recommendations on how to do that to you very soon. Meanwhile we would offer the following recommendations:

- Create a home and community-based care benefit that may be more limited in scope, giving states the options to target benefits to specific populations, lengthening the phase-in period, and requiring those individuals who can afford it to pay more for their care.
- Ensure that the home care benefit is available in homes and senior housing programs, as the President's proposal does.
- Expand Medicare to cover nursing facility care after an initial deductible period of 12-24 months. Individuals would finance the nursing facility "deductible" period through personal funding or long-term care insurance. Individuals with long nursing facility stays are at greatest risk of spending down their resources and becoming eligible for Medicaid. We believe that a "back-end" approach to nursing facility coverage would limit government costs of the benefit, while providing strong incentive to self-insure for those who are able. Clearly, cost is a major deterrent to the purchase of private long-term care insurance. Limiting exposure to shorter term nursing facility stays should make private insurance less expensive. Combined with tax incentives, that should be effective in making individuals more likely to purchase long-term care insurance.
- Increase protection to ensure adequate Medicaid payments, so that nursing facilities can provide services to meet the highest practicable well-being of their residents. Without such additional protection. Medicaid payments to nursing facilities will erode, and so will the quality of care provided to Medicaid beneficiaries.
- Include extended care benefits as an integral part of the basic health benefit package.
- Oppose maintaining the freeze on Medicare skilled nursing facility cost limits.
- Enact minimum standards for long-term care insurance, as the President's bill would do, in order to ensure coverage of basic benefits, promote

greater consistency across products to aid consumers in comparison shopping, and protect consumers by assuring the financial stability of products and markets.

- Create incentives for long-term care insurance through tax clarifications, as the President's bill proposes, thus providing economic incentives to purchasers and sponsors of these products.
- Promote education about long-term care—both risks and resources available to protect against risk. There continues to be significant misunderstandings, with the public overestimating the amount of long-term care coverage provided under Medicare, but underestimating the value and affordability of private insurance policies. Such education will be even more crucial if health reform is enacted with a "long-term care" benefit that does not expand nursing facility coverage. The elderly have reacted vehemently when they have discovered that legislation that was touted as providing significant new benefits did not, in fact, provide the benefits they sought. We would hate for health care reform to experience a similar fate.
- Defer to state discretion in regulation of CCRCs. In the event Congress determines to include regulation of CCRCs as long-term care insurance, Congress should include accreditation as an option in lieu of regulation.
- Preserve tax-exempt status for non-profit providers of health care services. While I recognize that this issue is not within the jurisdiction of this Subcommittee, Mr. Chairman, I would like to call attention to the relationship of not-for-profit tax exempt status to health care reform. Questions have been raised regarding the role of not-for-profit providers when health care reform has resulted in universal coverage. Please remember that without an increased benefit for nursing facility services, the Clinton long-term care plan will do little to solve the problem of many indigents and near-indigents who will still need nursing facility services. Unlike hospitals, nursing facilities will still have many needy individuals who fall into the "no care" zone, and not-for-profit nursing facilities will be caring for many of those individuals.
- Promote and support demonstration projects regarding long-term care delivery and financing, as outlined in the Administration's plan. Specific areas that should be explored include:
  - + Senior housing and residential care programs that provide supportive services for the frail elderly through the co-location of housing and supportive services, the establishment of long-term care provider networks, etc.;
  - + Greater flexibility in the use of Medicaid funding for supportive services; and
  - + Pooling resources across a wide range of public and private sector programs to reduce barriers to care and increase the cost-effectiveness of delivery.

Mr. Chairman, we must take the steps necessary to develop the kind of financing and delivery system capable of meeting the needs of a burgeoning elderly population in which a growing segment is becoming increasingly frail. And we must take those steps within current budgetary and political realities. The President's Health Security Act is a major step in the direction of more rationally meeting these needs, and we hope that you will consider the improvements we have suggested. AAHA stands ready to assist the Congress as it continues the vital task of reforming our nation's health care system.



Mr. WYDEN. All of you made excellent presentations. Let me ask one question for the first four, Mr. Wessel and Ms. Grigsby, Mr. Born, Ms. Ansak, and then we will get down to you, Dr. Willging and Mr. Goldberg.

For you first four, it has been a great concern of Chairman Waxman and I over the years that a number of the programs that we care about most have had a significant potential for fraud and abuse. We have seen, for example, even with the limited package of services that has been available through Medicare, significant instances of fraud and abuse.

Now, the President's proposal for home- and community-based services allows States to provide a wider variety of benefits ranging from homemaker services to the respite care program to even cash payments to individual patients. What we are interested in is how you would evaluate the Clinton proposal in terms of making sure that it does have the tools to deal with these problems of fraud and abuse. We want to make sure that people aren't getting more than they actually need, are not getting enough of what they need, are getting services of poor quality, and the question is, what are the tools in this bill to deal with the potential for fraud and abuse given the fact that even the record shows that the smaller program under existing Medicare had some significant problems with fraud and abuse? Mr. Wessel.

Mr. WESSEL. Speaking for myself and the National Association for Home Care, there are some concerns with the bill that we have some problems with, with individuals being able to purchase the service from other individuals, individual providers.

The bill, as I recall, specifically stated that employees of provider organizations needed to meet certain standards that weren't defined ever, which is another problem, but these individual providers not only weren't required to meet any standards of training or supervision, there was wording in there that prohibited the States from establishing standards for the individual providers. That is a serious problem.

You were asking for the potential of fraud and abuse that you are talking about, but by allowing that sort of language in the bill—at least let States keep in place the mechanisms they have now to oversee those kinds of programs. Don't prohibit the States from—those States that have mechanisms that work from using them. That is asking for more trouble. Individual providers, as a concept, is a problem with fraud and abuse and we don't feel it is a good one.

Mr. WYDEN. Ms. Grigsby.

Ms. GRIGSBY. Thank you. I share the concern with the challenge faced in the proposal by the issue of choice. Clearly, that is very important to persons who use these services. They need to have some sense of choice or the ability to select the caregivers and the services they need, but I also share Mr. Wessel's concern that some set of standards must be applied to protect the patient.

Yesterday's news in Los Angeles featured a young man who was quadriplegic who had hired someone independently to be his caregiver. Within 2 weeks, this person had bled out his bank account and had disappeared with his specially adapted van. Apparently, the individual felt he had no means of getting qualified or



screened help and he wound up vastly worse off as a result of a poor choice of someone to care for him.

We need to protect people who need this service from the opportunities that will be taken advantage of if we don't have safeguards in the program.

I think to your second point about how do we be sure the patients will have an adequate service to their needs, many of us have addressed the issue of case management. That is truly the responsibility in making sure that the individual's needs are assessed and the care plan is developed to those needs, it comes on an individual basis and not on the basis of simply a description or an eligibility category.

Mr. WYDEN. Mr. Born?

Mr. BORN. Not that that couldn't be a problem, and occasionally it has been, but we have a program that is \$50 million of our basic comp program is non-federally matched and then we have about \$25 million in Federal waiver money in the basic program and we need to match that.

So we have moved to a program that doesn't have all the rigid Medicaid requirements so that we can give consumers much more participation and choice and much more direction in the services, and I think we can't be paternalistic about that, and you do have to balance it.

In Wisconsin, our system is based on 72 counties. The money goes to counties. They have case managers as another level of government. They oversee the program. They authorize the services. Money may go to a person with a physical disability, but there is still some assistance and some management of that. And we have even overcome the problem of withholding tax and doing all of the book work by allowing counties to be agents for those people. So a lot of these problems do come up and we have addressed them with the kind of flexible system that we do have in Wisconsin.

Mr. WYDEN. Ms. Ansak?

Ms. ANSAK. Well, PACE being the kind of managed care program, we don't really—we don't see this. We don't hire—hire out individual participants or patients do not hire their own attendants. We provide them.

But we do see a lot of abuse in traditional programs, particularly in our area in San Francisco, where people can hire their own attendants, where there is no supervision and no real management in any way. This falls away from the PACE project, is very closely supervised, either through its multidisciplinary team, which is all organized through the various projects, and then the individual projects are being evaluated by the community health accreditation program, the League of Nursing that looks at it particularly since it is a managed care program, since it is an HMO-type of capitated program that could be abused. But we have built in those in our protocol, and with the way we are organizing it with the supervision through—or the evaluation or accreditation by CHAP, that there is basically no abuse.

Mr. WYDEN. We will want to work closely with you, because I have been concerned about the problems that we have had in the modest Medicare program. I am hearing from providers now that they are concerned that some real fast buck artists are going to

move to the home care area and I think we have got a problem, both with serious potential for fraud and just people simply not knowing what to do and not training a case manager properly, for example, and not having proper oversight of them and some people really getting hurt, so we are going to want to work closely with you four in particular to get your input on dealing with fraud and abuse.

One other question for you, Ms. Ansak, and I think you heard me say, I think PACE is a terrific program and I have been there many times, to your program in Portland. Why do you think it is so important now to initiate legislation to expand PACE?

Ms. ANSAK. Well, first of all, if you ever go into some long-term care program, there are really not enough organized kind of community-based long-term care programs. If you authorize any legislation which would pay for these programs, you are going to be hard up to find the kind of providers that are providing comprehensive and responsible types of care. The other thing, of course, is where is long-term going to go in the overall of the health care? You know, it could fall in between the tracks and we wanted to be sure that all the efforts that have been made by this committee and by all the PACE projects, that it doesn't get lost.

The third issue is that we have enormous—we have—we are working now with about 30—we have 15 projects that are in various stages of development. We have about 30 other organizations that are interested in developing PACE projects, plus Wisconsin and Massachusetts want to replicate it on a State-wide basis.

Because it is presently still in ORD, research and demonstration project, it has to go through OMB. Each individual project has to be authorized by them before we can even move ahead. So this is a real bottleneck. We need to be able to move ahead and prepare this program so that when Congress, perhaps after another 20 years, really legislates long-term care and a long-term care benefit, that we have these programs in place.

Mr. WYDEN. Let me ask just one question of you, Dr. Willging, and you, Mr. Goldberg, and that is your assessment of how the Clinton legislation is going to affect resident transfers and whether it is going to cause people to be moved from one program to another.

I think I have talked about this issue with both of you over the years. I am of the view that the demographic trends are so clear, that there are clearly going to be so many more older people in our society, that we are going to need a great deal more of all of the services, just all the way down this panel from Mr. Goldberg's program to the programs Dr. Willging represents to the home- and community-based programs.

I am of the view that for the long term, we are going to need a great deal more quality services in each one of those categories, and I have always been somewhat frustrated as we thrash through all these bills in the Congress that there is a concern about how people can game the system under one particular legislative initiative or another.

I gather—let me start with you on this, Mr. Goldberg. You are concerned that the States may get into the business of gaming the approach that the President is talking about? The President, in

your prepared statement, seems to say that the States would have an incentive to move some of their Medicaid nursing home residents into home- and community-based care in order to receive a higher Federal matching payment, limitation being that the transfer isn't a good idea. Is that your concern?

Mr. GOLDBERG. I think there are some wonderful opportunities with resident transfer. Oftentimes nursing homes are like a one-way direction. I think this type of a program gives the opportunity for people to go to the nursing home for proper medical care, rehabilitation, perhaps subacute care, and also the ability to go back into the community with resources that are available through this home- and community-based services program. It presents a very unique opportunity to have people move in and equally move out back into the community.

I see more and more focus in the nursing home on rehab, rehabilitation of people, getting them back to higher functioning, the subacute care. I see it having an ability of creating a focus, a tie to the community. My concern is they will diminish the reimbursement to the existing nursing home resident by taking a higher match, simply just devalue the reimbursement system that is going to the nursing home resident. That is my primary concern.

I want to preserve both, that there are community-based services and also that there is quality reimbursement to promote proper rehab and proper care of individuals within the nursing home setting.

Mr. WYDEN. Dr. Willging, your thoughts on this, included in your thoughts, the committee has been interested in trying to get a sense of the estimate of the number of residents who are in nursing homes who might be more appropriately cared for at home. Why don't you see if you can tackle both of those?

Mr. WILLGING. Let me start by agreeing with you 100 percent in your preliminary comment to the question, Mr. Chairman. There is no question that the need far outstrips current capacity and supply across the entire continuum of care. I think anyone who really is a reasonably astute student of long-term care recognizes that whatever we may have thought in years past, the various components of that continuum are not in competition.

I don't feel threatened or in competition with home- and community-based and indeed the vast majority of my members are already providing home- and community-based services as a part of what they do. So I think those days are behind us, as long as decisions in terms of placement along the continuum are made based on the needs of the resident rather than the needs of the treasury.

And, quite frankly, we are very worried about this different matching program, the 78 to 95 percent for the proposed home- and community-based services program as compared to the traditional 50 to 78 percent under the Medicaid program. I don't know of a State Medicaid director out there who would not look to that as a real boon for State finances to be able to take that resident out of one setting where the return is, in fact, only 50 cents on the dollar and put that individual in another setting, no matter how inappropriate for that individual, where the return might be 95 cents on the dollar. I think that is simply the way the game is played out



there. I do believe that that is one of the basic flaws in the program.

If indeed decisions are made based on the needs of residents, if decisions are made based on the appropriate care in the appropriate setting, I think, as you said yourself, Mr. Chairman, there should not be a problem in terms of competition, if you will, between these various segments on the continuum.

Mr. WYDEN. What are your estimates of the number of nursing home residents who might be more appropriately cared for at home? Again, getting us away from the competitive model, but just your analysis on that point?

Mr. WILLGING. I think it is at this point, today, a fairly small number, a very small number. I would also have to say that 10, 15, 20 years ago, figures as high as 35, 40 percent were bandied about. They may have been close. I recall in States like Texas where we had ICF's one, two, three, by the time you got down to the ICF level three, I think we were talking about residents who probably were better served in another setting in another location.

Given what has happened to nursing home residents over the last 15, 20 years, an average age of 85, ADL dependency, four out of five of the ADL's who suffer denial dementia, I think it is a small percentage. I suspect it is in the single digits.

Mr. WYDEN. OK. You all have been great. We still have another panel to go, otherwise I would ask you a lot more questions on the kinds of things you all are doing. I think they are some of the most important services in health care and I have an interest in them since the days with the Grey Panthers, and we will be working real closely with you in the days ahead. Thank you.

Next panel, Margaret O'Kane, President, National Committee for Quality Assurance; David M. Bee, M.D., Board Member, American Medical Peer Review Association; Bob Berenson, M.D., Medical Director, National Capital PPO; Dennis O'Leary, M.D., President, Joint Commission on Accreditation of Health Care Organizations; and Ms. Geraldine Dallek, Executive Director of the Medicare Advocacy Project.

We welcome all of you. I have had a chance to work with many of you over the years and have appreciated the opportunity. We will make your prepared remarks a part of the record in their entirety so we will have plenty of time for questions, and would like to ask you again to stay within 5 minutes.

Ms. O'Kane, welcome.

**STATEMENTS OF MARGARET O'KANE, PRESIDENT, NATIONAL COMMITTEE FOR QUALITY ASSURANCE; DAVID M. BEE, MEMBER, BOARD OF DIRECTORS, AMERICAN MEDICAL PEER REVIEW ASSOCIATION; ROBERT A. BERENSON, MEDICAL DIRECTOR, NATIONAL CAPITOL PPO; DENNIS S. O'LEARY, PRESIDENT, JOINT COMMISSION ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS; AND GERALDINE DALLEK, EXECUTIVE DIRECTOR, CENTER FOR HEALTH CARE RIGHTS**

Ms. O'KANE. My name is Margaret O'Kane and I am the President of the National Committee for Quality Assurance.



We are pleased to have the opportunity to testify today before the subcommittee on the important topic of quality and health care reform.

To monitor and ensure quality, NCQA proposes a public accountability system using two complementary efforts: An accreditation process and public reporting of performance measures. This approach is consistent with the President's health care reform legislation and mirrors the current efforts of NCQA.

We believe the goals of an accountability system include, first, consumer protection and appropriate access to care; second, continuous improvement in quality; and third, consumer access to information on quality.

NCQA believes that both an accreditation process and the performance measures are critical to ensuring the delivery of quality care and service. The accreditation process ensures that minimum standards are met and that the plan is continuously pursuing quality improvement. And for the first time, the report card provides the opportunity to compare health plans on specific aspects of their performance.

We recommend that national entry requirements be established for all health plans, indemnity and managed, and that the requirements be increased each year. Implementation should be continuous, with more measures to be added as our ability to measure improves and as health plans develop the information systems needed to produce the data.

The President's plan embodies a number of the principles NCQA believes are necessary for a strong quality component in a health care reform environment. First, the proposal makes an important and crucial change. It moves away from a punitive "find the bad apple" approach and moves to a systematic performance-based system for measuring and encouraging improvement in quality. Then consumers will be given information on specific health plans so that they can make informed decisions about quality and cost.

An area that is virtually unexplored is the information needs of consumers. We do not know either the types of technical quality information that will be compelling to consumers or how the information should be presented so that it is understandable. We are currently working with consumers to find out what it is they want to know and how best to present it.

NCQA strongly believes that all health plans should be accountable for quality regardless of their financing and delivery structure. With both managed and fee-for-service health plans operating in the proposed system, minimum quality elements should be in place to monitor all services and medical delivery.

Our accreditation program evaluates the extent to which a health plan has a delivery system which supports high-quality patient care and is continuously improving. The process also ensures that basic protective and monitoring systems are in place for problems which do arise.

Another important goal of the accreditation program is to consolidate multiple review processes which health plans often must undergo today. Eliminating the duplication will free time and resources at the health plan for real quality improvement. We look at an organization's quality improvement program, credentialing

activities, utilization management system, preventive health services system, medical records, and systems for ensuring member rights. We also include physician review of medical records in order to assess the quality of care being delivered by the health plan.

Let me talk about performance measures. A framework for assuring the accountability of health plans should also include the public reporting of comparable data on various aspects of performance. The President's plan appropriately reflects the dynamic nature of this area and requires that Federal boards set priorities and usually make changes to the national performance standards as necessary.

The development of such measures is an ongoing process. The performance measures that already exist have high consensus in the medical community and a strong scientific base. This is not true, however, for a broad range of other procedures and services for which we do not yet have measures.

In November, NCQA released the health plan employer data and information set, a core set of performance measures that were defined by a combined group of major employers and health plans. The components included quality, access, patient satisfaction, utilization and finance.

NCQA has a report card project using a subset of these measures and the participants include 21 of the country's largest and most prominent managed care organizations who will be reporting their data out in a prototype report card at the end of this year.

While some individual health plans have their own impressive report card initiatives, NCQA believes it is critical that there be a national comparative report card and that the information be audited. Based on our experience with HEDIS and other measurement projects involving a modest number of health plans, we believe that a carefully thought out implementation strategy with goals and schedules must be established for any kind of national initiative.

We also hope you will look at work already done, such as that that we are doing with our HEDIS project.

Mr. WAXMAN. Thank you very much. The rest of that is going to be in the record.

[Testimony resumes on p. 422.]

[The prepared statement of Ms. O'Kane follows:]

**STATEMENT BY**  
**MARGARET O'KANE**  
**PRESIDENT, NATIONAL COMMITTEE**  
**FOR QUALITY ASSURANCE (NCQA)**

My name is Margaret O'Kane and I am the President of the National Committee for Quality Assurance (NCQA). We are pleased to have the opportunity to testify today before the Subcommittee on the important topic of quality and health care reform.

NCQA promotes improvements in the quality of patient care provided by managed health plans through development and application of specific, detailed principles for continuous quality improvement and measures of performance for health plans. NCQA is committed to providing information on quality to the public, consumers, purchasers, health plans, and state and federal government. Governed by a Board of Directors of managed-care executives, purchasers, independent quality experts, and union and consumer representatives, NCQA represents a unique collaborative partnership through which to implement effective mechanisms to monitor and improve the quality of care and services.

To monitor and ensure quality, NCQA proposes a public accountability system using two complementary efforts: an accreditation process and public reporting of performance measures. This approach is consistent with President Clinton's health care reform legislation and mirrors the current efforts of NCQA. The goals of an accountability system include:

- Consumer protection and appropriate access to care
- Continuous improvement in quality
- Consumer access to information on quality

The accreditation process assesses how well a health plan has established management structures and processes to monitor the quality of patient care and member service, and verifies that the structures and processes are functioning to deliver an acceptable level of quality and to continuously improve it.

Public reporting of performance measures or "report cards" will give consumers and purchasers more information on specific aspects of health plan performance in order to make informed choices about health plans. This information will also give policymakers the means to gauge progress towards public health priorities. Performance measures address medical care processes and outcomes, accessibility and service, and member satisfaction. Comparable data from health plans will be compiled into report cards to facilitate health plan comparisons by consumers and purchasers. The report card concept is being piloted by NCQA in 21 of the country's largest and most prominent health plans using a core set of Health Plan Employer Data and Information Set (HEDIS 2.0) measures.

NCQA believes that both the accreditation process and the performance measures are critical to ensuring the delivery of quality care and service. The accreditation process ensures that minimum standards are met and that the plan is continuously pursuing quality improvement. The report card provides for the first time the opportunity to compare health plans on specific aspects of their performance.

We recommend that national entry requirements be established for all health plans, indemnity and managed, and that the requirements be increased each year until all plans are subject to a full range of accreditation standards. We also recommend that initial reporting on performance measures begin. Implementation should be continuous, with more measures to be reported on as medical research supports their validity, and as health plans develop the information systems needed to produce the data. Let me discuss these points in more detail and describe what NCQA activity has been in these areas.

#### Quality and Health Care Reform

The Clinton health care reform proposal embodies a number of the principles NCQA believes are necessary for a strong quality component in a health care reform environment.



(Please see the NCQA principles which are attached).

First, the proposal makes an important and crucial change -- it moves away from the punitive "find the bad apple" approach and moves to a systematic, performance-based system for measuring and encouraging improvement in quality. Then, by requiring health plans to collect and report comparable data on performance, consumers will be given information on specific health plans so that they can make informed decisions about quality and cost.

### Consumer Needs

NCQA believes that consumers and purchasers have the right to make informed choices among health plans and that these decisions should be based on quality as well as cost. That is why NCQA has devoted so much time to HEDIS 2.0 -- a report card developed with health plans and purchasers. However, an area that is virtually unexplored for both accreditation and report cards is the information needs of consumers. We do not know either the types of technical quality information that will be compelling to consumers or how the information should be represented so that it is understandable to consumers. A dialogue with consumers must be initiated and pilot testing must be performed to determine what consumers want to know in order to guarantee that the goals of public reporting are accomplished. Specifically:

- What information do consumers want and need in order to select among competing health plans?
- What is the most consumer-friendly way to present this information?

NCQA believes that no one -- neither consumers nor health care experts -- currently has the answers to these questions. Although minimal work has been done to determine what consumers want to know, significant progress has been made in producing information for purchasers, particularly when it comes to performance-based report cards. NCQA has received support from the Commonwealth Fund to initiate a major consumer-focused research project.

The receipt of The Commonwealth Fund planning grant is a first step toward a larger project that will help NCQA to develop more consumer-focused report cards, thereby helping to foster greater public accountability within the health care system. Accountability is a theme echoed by most, if not all of the various health care reform proposals which envision consumers choosing among competing plans based on cost and quality.

The research for the planning grant has involved a literature review, interviews and a focus group with consumers to test methodology and develop an initial list of consumer issues. These steps will enable NCQA to design a proposal for the main project which would include: a methodology for producing, prioritizing, and validating a list of consumer issues; and the steps necessary to develop, test, and produce useful, consumer-friendly information. This main project, anticipated to begin in April 1994, will allow NCQA to identify consumers' values when it comes to assessing health care, as well as to determine the information needs of particular groups such as the elderly and the chronically ill.

#### Requirements for all Health Plan Structures

NCQA strongly believes that all health plans should be accountable, regardless of their financing and delivery structure. With both managed and fee-for-service health plans operating in the proposed system, minimum quality elements should be in place to monitor all services and medical delivery. Even less structured delivery systems such as indemnity plans should be required to: credential their providers; monitor both insurance and health delivery complaints and grievances; implement standards for utilization management; and provide data about member satisfaction and clinical performance. All health plans must be able to provide data on quality performance, or the more structured plans that do have data will be at a disadvantage in the marketplace.

NCQA recommends establishing basic "entry" requirements for all health plans, both indemnity and managed, and increasing these requirements annually until all accreditation standards can be applied to all plans. This will serve as a mechanism to encourage indemnity health plans to make a transition towards more effective management. In addition to basic "entry" requirements, NCQA recommends establishing standard quality reporting requirements to be used by all health plans. These requirements must be phased in gradually to allow health plans to develop the necessary internal information system capabilities. The implementation of information systems in health plans to collect the data needed to produce performance measures is an ongoing process. Many health plans will require some years to establish these systems.

Policy makers must strike a balance between the desired types of quality measurement and the ability of health plans to meet these requirements. If the requirements are too minimal, quality will be compromised. However, quality requirements that lack practical applicability may undermine a reformed systems's likelihood of success.

Quality oversight systems and measures will drive health plan behavior. It is essential to carefully consider the incentives in potential monitoring strategies in order to make successful quality performance consonant with public health priorities. Performance requirements should hold health plans responsible for appropriate care to their entire population. Quality requirements should be based on indicators that emerge from the efficient functioning of effective delivery systems.

As previously mentioned, NCQA believes that to monitor and ensure quality under any reformed health care system, there must be a public accountability system using two complementary efforts: an accreditation process and public reporting of performance measures. We are concerned, however, that the Administration proposal appears silent on the role of accreditation.

Both the accreditation process and performance measures are critical to ensuring the delivery of quality care and service. As stated in the Physician Payment Review Commission's (PPRC) draft chapter on quality, "information from report cards alone may not drive plans that provide inferior quality out of the market; external monitoring and controls may be necessary." Accreditation is vital to ensuring that a given health plan thoroughly investigates its providers, is responsive to member grievances, has a system that ensures appropriateness of care and performs other critical functions.

#### The Accreditation Process

Evaluation of the effectiveness of a health plan's internal systems, through external review and accreditation, provides information on the extent to which a health plan has created an environment supportive of high quality patient care, and the ability of the health plan to continuously improve its performance. The process also ensures that basic protective and monitoring systems are in place for the problems which do arise. Such information is crucial as consumers and purchasers make choices among competing health plans.

Another important goal of the accreditation program is the consolidation of multiple review processes which health plans often must undergo. Eliminating the duplication of efforts caused by repetitive external reviews will free time and resources at the health plan for substantive quality improvement activities. This also decreases the total cost of federal, state and employer reviews. We would caution that under a "reformed" system where there are potentially separate federal, state and alliance quality requirements, that care must be taken so these not be substantially different, nor duplicative and burdensome.

NCQA's accreditation review process includes a structured survey of an organization's quality improvement program, credentialing activities, utilization management, preventive health services, medical records, and systems for ensuring member rights. The accreditation process



also includes physician review of medical records in order to assess the quality of care being delivered by the health plan. The standards are not "entry level." The survey is conducted by a team of highly qualified managed-care professionals using NCQA standards. Upon successful completion of the NCQA accreditation program, a managed-care organization receives a three-year accreditation. Alternatively, a plan which receives provisional accreditation is reviewed again within one year. NCQA provides detailed recommendations to provisionally accredited plans to help them move to full accreditation. Approximately 77 percent of the health plans reviewed to date received provisional status, 18 percent have been fully accredited, and five percent were denied.

At present, a number of major national employers require NCQA accreditation for all the HMOs they offer, including Allied-Signal, Ameritech, GE, GTE, Pepsico, Procter & Gamble, UPS, and Xerox. Many other employers like General Electric, IBM, Mercantile Stores, and USAir strongly recommend that their health plans become NCQA accredited.

In addition to major employers, the states of Kansas, Florida, Pennsylvania, and Oklahoma now require external review for all their HMOs and have approved NCQA as an external reviewer. Other states are evaluating the NCQA accreditation program and may accept its review process in addition to, or in place of their own.

While our accreditation program is new, having begun in 1991, by the end of 1993 we completed accreditation reviews of over 150 managed care organizations nationally. More than 90 new reviews are scheduled for 1994.

#### Performance Measures

In addition to an accreditation program, a framework for assuring the accountability of health plans should include the public reporting of comparable data on various aspects of performance, as previously mentioned. Such a system will serve to: 1) provide health plans with

"benchmarking" information to identify areas of improvement; and 2) provide consumers, purchasers and regulators with information to assess health plan performance.

The Clinton health care reform proposal appropriately reflects the dynamic nature of this area and requires that the National Health Board and the National Quality Management Council annually make changes to the national performance standards as necessary. The proposal also rightly directs that a five-year priority list of performance measures be established and that federal dollars be spent to support research that focuses on the area of measuring quality of care.

It is important to note that the development of such measures is an ongoing process. The performance measures that already exist, such as those for most preventive health services, have high consensus in the medical community and a strong scientific base. However, measures of a range of other procedures and services have not yet achieved the level of validity and consensus which should be attained before being included as national standards for performance. Quality indicators for cardiac care are one example. Implementing comprehensive measures of quality for a broad array of acute and chronic conditions is a goal for the next several years. We expect to see an increased focus on outcomes measures as medical research establishes more linkages between the delivery of care and its outcomes.

Let me describe NCQA activities in this area. In November, NCQA released the final version of HEDIS 2.0, a core set of performance measures that were defined by a combined group of major employers and health plans. This effort began in 1992, when NCQA was asked to coordinate the project.

Specific components within HEDIS 2.0 are:

- Quality - measuring the health plan's performance in the delivery of certain selected services. These include:

1. Preventive Services

2. Prenatal Care
3. Acute and Chronic Disease
4. Mental Health

- Access and Patient Satisfaction - measuring performance in member access to care and satisfying members;
- Membership and Utilization - measuring performance regarding membership stability and demographics as well as resource allocation within the plan; and
- Finance - measuring performance in achieving financial stability.

As HEDIS 2.0 gains widespread acceptance, it will assist health plans in their quest for a common set of reporting standards that will satisfy the needs of multiple users. Standardized definitions and specific methodologies for deriving performance measures, as outlined in HEDIS 2.0, will enable plans and employers and others to accurately trend health plan performance, and as the measures are refined, use them in a comparative manner.

HEDIS is only the first step toward the development of a system of comparable performance measures on health plan quality. As future improvements in methodologies and underlying data systems are made, plan data will become more reliable, and more measures will be developed for report cards on health plans.

We have also been involved in the Michigan Project, a collaborative effort involving Ford, GM, Chrysler, the United Auto Workers' Union, nine southeastern Michigan HMOs, and NCQA. This project is the first effort to collect standardized, comparable data, use a consumer satisfaction survey and accreditation. The data includes information on mammography, pre-natal care, childhood immunizations and access. The project's goal is to produce comparable performance data on each participating HMO for use by external customers such as the auto companies. The auto companies will use the information to ascertain the quality of care and

service delivered by their participating managed-care organizations. The information will be used to establish baseline data and benchmarks for HMO quality improvement, enhancing opportunities for HMOs to demonstrate to their major employer groups their successes in improving the quality of their care and service.

The Administration's proposal requires that the National Health Board "establish a performance-based program of quality management and improvement designed to enhance the quality, appropriateness, and effectiveness of health care services and access to such services" not more than one year following enactment. As we have discussed, the whole area of quality measurement is a relatively new one and certainly dynamic. While NCQA is on the cutting edge in terms of what we're doing with managed care organizations, our projects with HEDIS 2.0 and the Michigan Project are relatively new.

Based on our experience with these projects, which involve modest numbers of health plans, NCQA believes that a very carefully thought out implementation strategy, with goals and a careful phase-in schedule, must be established for any kind of national initiative. Further, whichever body is ultimately responsible for establishing national quality standards or requirements, we strongly suggest that advantage be taken of the work already done. You may want to direct them to look at and use HEDIS 2.0, for example.

The National Quality Management Council under the Clinton plan is also responsible for periodic consumer surveys. Where the survey is to deal with access, use of health services, health outcomes, and patient satisfaction, we would suggest that there are already excellent surveys in use which address these areas.

#### Conclusion

The Clinton health care proposal makes the important and necessary step of moving to a systematic performance-based system with national standards. The criteria cited in legislation



for selecting the standards are sound.

We don't question the need to establish goals and appropriate time schedules, but we are concerned that the timetable for implementing a performance system might be unrealistically rapid. The first goal of the quality component should be to protect consumers. As mentioned, whatever federal body is ultimately responsible for establishing a quality management program, it should look at work already done such as HEDIS 2.0 and consumer surveys. We are concerned that the Clinton proposal appears silent on the role of accreditation. Also, with the multiple layers of bureaucracy under the Clinton plan with the National Health Board, the National Quality Management Council, the states, the alliances and the corporate alliances, there is potential for a burdensome program which has either conflicting or duplicative quality requirements. The result might be a process which diverts resources from delivery of services.

We recommend the following:

- A public/private approach that builds on current work
- A quality accountability system using accreditation and performance measures
- Establishment of national standards
- Quality requirements for all health plans -- managed care and fee-for-service indemnity plans
- A carefully structured implementation strategy that provides a quick time frame for reasonable, short term goals and a priority list and phase in period for long term goals
- A system that is uniform and streamlined and avoids duplication and burdensome requirements resulting from multiple sets of requirements.
- A medical research system that works to inform what is effective in medical care and how to appropriately measure quality

Everyone agrees that there are flaws in our current health care system and that some reform is necessary. NCQA is committed to working with the members of this subcommittee, the Administration, health plans, employers, consumers, and regulators to assure that the quality component of any reform proposal meets the goals that we all agree on -- assuring quality, continuous quality improvement, and accountability.

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# NCQA

## *NCQA PRINCIPLES ON QUALITY AND HEALTH CARE REFORM*

The National Committee for Quality Assurance (NCQA) believes that consumers and purchasers have a right to make informed choices among competing health plans based on cost *and* quality. Cost is relatively easy to assess while gauging quality is a more difficult undertaking. NCQA supports responsible evaluation and reporting about health plan quality.

Specifically, NCQA believes that quality and health care reform should be guided by the following five principles:

### *I. Public Reporting*

Health plans and outside organizations have a responsibility to publish meaningful, accurate and consumer-friendly quality information.

### *II. Accountability*

Accreditation reviews and performance measures are inter-related, standard tools that purchasers and consumers should require to make health plans accountable for the quality of care and services they deliver.

Such standard accountability tools must be rigorously tested for reliability, and implemented and/or validated by an objective, outside organization.

These tools must be dynamic to respond to changes in the science and practice of medicine.

### *III. Continuous Improvement*

Accreditation reviews must give purchasers and consumers information about a plan's quality infrastructure, and provide a mechanism for the plan's self assessment and continuous improvement.

### *IV. Comparability*

Performance measures must be standardized to allow consumers, purchasers and regulators to make comparisons between health plans.

These measures should evaluate high-volume, high impact processes which serve as indicators of health plan quality.

### *V. Stakeholder Involvement*

Physicians and allied health professionals, as well as purchasers, consumers, regulators and health plans should be involved in generating ways to evaluate and measure quality.

Mr. WAXMAN. Dr. Bee.

### STATEMENT OF DAVID M. BEE

Mr. BEE. Thank you, Mr. Chairman. My name is David Bee. I am a board certified practicing internist who has recently become a full-time medical administrator for FHP, which is a multistate HMO, and am doing this after 20 years of bedside internal medicine and critical care practice in the fee-for-service environment.

I have been involved with external peer review for a great many years, was president of the California Peer Medical Review Association, which is a federally qualified peer review organization for California. I am a member of the Board of the American Medical Review Association who I am here representing today.

I appreciate the opportunity to participate in these important discussions. In particular, AMPRA would like to express its appreciation to you, Mr. Chairman, and to you, Congressman Wyden, for your leadership in putting the quality issue at the forefront of the discussion in health reform.

We have submitted a written report called Health Reform and the Quality Imperative, which we would like to request be part of the medical record. [The report referred to is retained in the file record of the subcommittee.]

Mr. WAXMAN. Without objection, we will make it part of the legislative record.

Mr. BEE. I am sorry. I am used to clinical records. Thank you very much.

There are four points that I would like to highlight that come from our written report today. The first one is, as a—let me explain it this way, as a medical director in a prepaid health plan, my job is to teach doctors how to provide high quality health care in an environment of restricted resources, or instead of admitting patients to hospitals and performing more tests and procedures and seeing more patients per hour, their income will go up by doing less of these things. I have to teach them how to do that and maintain a high standard of care at the same time.

Now, I think I understand quite well that at the present time about one of every five health care dollars is wasted on benefits that benefit only the providers of that care. But those of us who have spent 20 years in external formal peer review are aware that financial incentives are mighty, and as a recent personal consumer of a lot of health care resources, I am sure I need to be reassured that there will always be independent external review of the process, because I want myself and my family to be protected from loss of access and from loss of access to the magnificently high quality of medical care that we know that we can provide in this country.

Second, AMPRA recommends that external independent review be done via a national network of State based health quality foundations that are accountable to Congress through the National Quality Management Council. We believe that is the best way to ensure that health plans will be monitored for quality and for accurately reporting what they do.

We believe these independent State based organizations should be governed by an alliance of all the stakeholders in health care—consumers, purchasers and providers—who can best meet the need

to ensure consumers of the reliability of reported data and to provide the analysis of process and outcome which will be the basis for continuous quality improvement across all segments of health care delivery. These data, properly analyzed and fed back to the health plan, to the providers, to the physicians and the community will then be the basis for educationally driven change rather than a regulatory model of imposed control.

Third, we believe that this opportunity this year to create a broad based, all payer data system to support this process of continuous quality improvement must not be missed. Regardless of the form your legislation ultimately takes, the need to find out what is done to patients and what are the results to these patients needs desperately to be captured, studied and fed back to the providers if we are realistically going to meet the goal of lowering cost by improving quality.

Fortunately, the President has made an excellent beginning toward ensuring quality with his recommendations for regional professional foundations. However, we believe unless supported by data and analysis about health care that is actually being delivered, this will be little more than an enhancement of the continuing education programs now offered by our medical schools.

AMPRA recommends instead that the current program of extensive linkages of our medical schools to the currently funded Medicare quality review organizations now in place be enhanced and integrated into the health quality foundations we urge you to create for the health care system as a whole.

We recommend, first, independent external review with committee-based programs. My time is up. Thank you very much. Appreciate your time.

Mr. WAXMAN. Thank you very much, Dr. Bee.

[Testimony resumes on p. 435.]

[The prepared statement of Dr. Bee follows:]



Written Statement  
of the  
American Medical Peer Review Association

Introduction

Mr. Chairman and members of the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, my name is David M. Bee, M.D., F.A.C.P. I am a board certified practicing internist who has recently become a full time Medical Administrator for FHP (a multi-state HMO) after 20 years of bedside internal medicine and critical care practice. I am also a Past President of the California Medical Review, Inc., the Medicare contractor for quality oversight in California, and am presently a member of the board of directors of the American Medical Peer Review Association, the national association of independent quality evaluation organizations, including the federally designated Peer Review Organizations (PROs). I have been involved with formal external peer review and quality evaluation activities since 1974. I appreciate the opportunity to participate in these important discussions.

In addition to this prepared written statement, I submit for the record a just released AMPRA policy report entitled, *Health Reform and the Quality Imperative*. Our following written statement highlights the primary recommendations contained in this policy report.

Health Reform and the Quality Assurance Imperative

A decade ago, called to action by unrelenting medical care cost pressures, Congress enacted a radically new prospective payment system (PPS) for the Medicare program. Fixed payments for

hospital admissions were introduced based on Diagnosis Related Groups (DRGs). Overnight, financial incentives for hospitals were altered with hospitals rewarded for tight management of inpatient days and operating costs. Congress, concerned about the impact of these new financial incentives on patient care, enacted a comprehensive quality monitoring system through Peer

Review Organizations (PROs). The potential for undertreatment, premature discharges, gaming of the DRG coding system, and inappropriate hospital admissions were closely monitored as an active and ongoing safeguard against compromises to patient care quality.

Ten years later, the debate on health reform is raging with the prospects never better for enactment of some form of comprehensive legislation before the mid-term elections of 1994. As before, medical cost pressures are driving much of the debate and new reimbursement mechanisms are being sought to promote increased efficiencies in the delivery system. Under both President Clinton's proposed Health Security Act and the plans being promoted by the Senate Republican Task Force on Health and the House Conservative Democratic Forum, medical care received by Americans will be delivered by competing health plans receiving fixed per capita payments from regional and corporate alliances. The downward pressure on plan revenues exerted by a capitated reimbursement system, competition with other plans, and the potential for explicit premium price controls provides rich incentives for undertreatment that parallel the prospective payment system for Medicare. Only this time around, the financial incentives will be on a more far reaching basis touching all health care services and the entire patient population.

Mr. Chairman, there can be little doubt in my mind that such a reformed health care delivery system will need an active and ongoing quality monitoring and assurance system. In a recent policy pronouncement, the Institute of Medicine writes:

...the paradigm shift calls for health plans to provide needed services to a population in the face of stringent resource constraints, and the incentive will likely be to underserve people. These changes make monitoring the quality of care imperative, especially for the sickest individuals and other at-risk populations. (*The Journal of the American Medical Association*, October 27, 1993, p. 1911)

In a managed competition system, health plan profits will depend upon how much or how little they spend on delivering care. Checks and balances are crucial to managing quality for the nations most vulnerable -- the sick, disabled, chronic and terminally ill, and poor urban and rural populations. The transition to managed competition must support quality of care protection for consumers, promote provider and practitioner continuous improvement, and provide community/state quality information about performance in this dramatically different health services delivery system.

Mr. Chairman, I believe we must commit to assuring and improving the quality of care to all Americans as an explicit goal of health reform. But meeting this goal represents a formidable task that demands an equal commitment to a national quality monitoring and improvement system.

The Clinton Prescription for Quality Assurance

Mr. Chairman, designing a national quality oversight and improvement program to match up effectively against the new incentives that would be created under health reform based on managed competition is a major challenge. In its blueprint for health care reform, the Clinton Administration begins to build a national framework through the design of a "National Quality Management Program." The plan has a number of positive features: the policy principle that health care plans are responsible for the improved health of the populations served; creation of a national health care information database that will serve as the foundation for quality related activities; enshrining the principle of meaningful consumer choice by promising consumers a "report card" that compares plans and providers within plans not merely on costs, but also on specific performance measures; the establishment of a state based patient complaint office to permit redress for consumers that feel their benefits have been curtailed by competing health plans; a renewed national commitment to patient outcome research and national practice guidelines.

However, the Clinton plan falls short of an active quality monitoring system that holds health plans and participating providers and practitioners publicly accountable for improved performance. In philosophy, the Clinton plan is too reliant on a theoretical construct that health care plans, given proper incentives, will compete on the basis of quality and that individual health care consumers, armed with meaningful quality data, will be discerning in their choice of plan, provider and treatment. While an elegant goal that needs to be aggressively pursued, I do not believe, Mr. Chairman, that we are close to protecting consumers through a quality based



competitive marketplace. For some time to come, most consumers will select a health care plan based on other factors, like price or which plan their own doctor joined, and will not be "walking with their feet" based on reading and comprehending performance measures in a consumer report card. Surely, it is hard to believe that the average health care consumer with a complicated condition is knowledgeable enough to realize that he or she is not being treated according to the accepted practice guidelines or that a patient admitted to the hospital for an acute illness will be fully cognizant of all the treatments he or she receives or should have received during an episode of care. Appealing to "medical professionalism" and establishing a consumer report is not enough to ensure a comprehensive national quality management program.

The latest version of the Clinton plan also substantially weakens the quality management function itself by penciling out the "state-based technical assistance foundations" which in the original proposal had been assigned with designing and implementing quality measurement and management systems. Instead, this state-based infrastructure was replaced with "Regional Professional Foundations" whose mission would be to develop programs in "lifetime learning" for health professionals. It is difficult to understand why a state-based, broadly representative quality monitoring and management system close to local markets, consumers and practicing health professionals was abandoned in favor of an academically led, continuing medical education and research initiative based at the regional level. Absent are any provisions for: data analysis and quality monitoring; external auditing of data self-reported by health care plans; community-based quality improvement initiatives for health plans and, within plans, to areas of greatest need; measuring, documenting and holding plans accountable for subsequent quality improvement on an ongoing basis; supporting the compilation of quality related performance measures in a

consumer report card; and most importantly, monitoring rates of adherence to national practice guidelines.

### Monitoring Adherence to Practice Guidelines

Most would agree that the current state-of-art in medical quality assurance circles lies with national practice guidelines. The science of risk adjusted outcomes measurement is still in infancy and frustrated by the difficult search for consensus. Guidelines based on clinical trials, outcome research and expert clinical consensus are generally more positively received by practicing physicians. By clarifying major areas of medical ambiguity, practice guidelines and their diffusion into medical practice should go a long way towards reducing practice variations and improving overall quality of care. What is all too rarely mentioned, however, is the need to develop and routinely apply guidelines-based quality review criteria to monitor whether they are being observed. With the increased incentives for undertreatment, the mere existence of a guideline will not ensure broad compliance.

Past research has shown that passive dissemination techniques are inadequate for transferring the scientific knowledge codified within practice guidelines into actual clinical practice. The collaborative medical review, research and clinical communities extensive experience in this arena has demonstrated that to sustain profiling and feedback activities it is necessary to have a central organizational structure with management expertise and responsibility as well as quantitative,

outreach, education and clinical skills. The expectation for continuous attention to quality improvement should have a concrete structure. This experience includes the development of numerous behavioral techniques (e.g. opinion leader education, small area analysis data feedback). Interactive CME in which different medical specialties review their own performance rate analysis and that of their peers in assessing their compliance to practice guidelines<sup>1</sup> is needed in order to implement self-initiated quality improvement. Continuous feedback and reinforcement of appropriate practice patterns are all methods and techniques which review organizations are presently managing and facilitating to measure the successes of guideline implementation processes. They are working with medical specialty groups, large multi-specialty group practices, Areawide Health Education Centers and others.

Performance measures for assessing and evaluating the impact of several specific practice guidelines (Urinary Incontinence (in females), Acute Post-Operative Pain, and Benign Prostatic Hyperplasia) are presently being implemented by the American Medical Review Research Center in collaboration with academic researcher, public health, and medical review organizations. The recently re-tooled Peer Review Organizations (PROs) now have staffs of biostatisticians, analysts, practicing physicians with advanced public health and quantitative degrees, evaluation experts and other experienced clinical professionals. They are serving as the "local intelligence, engine," and administrative mechanism within the community. These state-based groups have been uniformly trained for quality improvement work and for working with academicians and large groups practices. Historically academic centers and health services researchers have not embraced

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<sup>1</sup> Three State medical review organizations (MD, AL, IA) have completed this work in collaboration with three academic centers led by the Center for Quality of Care Research and Education at Harvard. This unique quality evaluation CME was coordinated by the American Medical Review Research Center.

program operation ventures.

Monitoring and evaluating practice guideline adherence has been shown to require careful translation, validity and consistency checks to assure the guideline content is completely and accurately represented. It would be unfair for a health plan to suggest elimination of procedures on the basis of their cost, when a portion of the guideline indicates its positive impact on quality. On the other hand if the evaluative exercise linked to outcomes demonstrates that in fact quality is not enhanced -- this is important information that needs to be fed back to the National Health Board, Alliances, and health plans.

#### AMPRA Recommendations

In the marathon race from health care reform proposal to enactment, vocal consumers will work tirelessly to ensure that quality of care will be closely monitored on their behalf. Here is what is needed at a minimum:

- 1. Quality monitoring and improvement activities should be integrated and coordinated through a nationally-directed but state-based network of independent Health Quality Foundations.** As currently written, the Clinton proposal fragments the responsibility for conducting quality activities among various federal, state and regional entities: Regional Alliances (report cards); state government (health plan certification and consumer complaints); the Regional Professional Foundations (continuing medical education and research); and the Quality Councils under the National Health Board (practice guideline



dissemination, consumer surveys). While ultimate responsibility for quality needs to be shared by government, purchasing, and health delivery entities, the Clinton proposal lacks an identified infrastructure that can integrate and coordinate community-based quality monitoring and improvement activities. It would make far more sense to establish for this purpose a national network of state-based Health Quality Foundations, broadly representative of consumer, purchaser and medical professional interests, with close communication and formal linkages to regional/corporate alliances, state government and the National Health Board.

Primary responsibilities of Health Quality Foundations would be to: monitor quality through data analysis and national practice guideline adherence; protect quality through holding plans and providers accountable for improved performance, through reporting findings and conclusions to appropriate purchasing and regulatory bodies (e.g. alliances, state government, National Health Board), and through providing medical consults to support the state patient complaint office; improve quality through the feedback of comparative performance data to health plans and participating providers; inform consumers about quality through developing a community-based resource for medical treatment alternatives and through the support of purchasing alliances in development of the quality related aspects of a consumer report card; assure data integrity by conducting external audits of the accuracy and reliability of the data self reported by health plans.

**2. Rates of adherence to practice guidelines should be monitored.** Established research and experience suggests that health plans and physicians will not conform their practice

behavior to practice guidelines merely because they exist. Although the experience of the PRO program in monitoring practice guidelines is recent, early experience suggests that the application of review criteria based on practice guidelines can serve as both an effective quality monitoring tool while providing a catalyst for plan and practitioner self-examination and improvement. PROs have the only existing infrastructure and increasingly the expertise in appropriate sampling, abstracting, and feedback methodologies to ensure that the process is scientifically-based, streamlined and non-intrusive to health plans and physicians.

3. **Quality management and oversight should be separated from, but closely coordinated with Regional and Corporate Alliances.** As the chief purchasing agents on behalf of purchasers and consumers, Alliances clearly hold whatever clout exists in a managed competition system to negotiate with health plans on the basis of quality. Under the currently proposed system in which the federal government would limit costs through budget caps and alliances through premium price controls, it poses a conflict of interest for a single entity to regulate both price and quality. Ideally, the quality measurement, monitoring, and improvement functions would be conducted by a Health Quality Foundation explicitly devoted to that purpose but working closely with the Alliance if sanctions, penalties, or cancellations of health plan contracts should become necessary.

### Conclusion

In the past decade, medical oversight and quality assurance methodology has evolved dramatically

in response to changes in payment incentives and in response to advances in the field of quality evaluation. As the dominant reimbursement mechanism changed from per diem to per case under DRGs and, as it now moves towards fully capitated systems, medical review is less concerned with excessive use and is focused now on adherence to guidelines, technical quality and the creation of safeguards against underutilization. PROs have been leaders in forging expansions in technical capability: moving away from contentious retrospective individual case review with its reliance on the vagaries of peer judgement to the effective manipulation of large quantities of data and toward increasingly sophisticated modeling of medical practice variation, patient outcomes, and practice guideline compliance.

In the exciting decade to come in medical care delivery, an independent quality monitoring system will be needed to hold the health care delivery system publicly accountable for assuring and improving the quality of care for all Americans. AMPRA and its membership look forward to participating in this critical component of national health care reform.

Thank you, Mr. Chairman, for the opportunity to testify.

Mr. WAXMAN. Yes, sir.

# STATEMENT OF ROBERT A. BERENSON

Mr. BERENSON. Thank you, Mr. Chairman.

Over many years my medical practice has had the privilege of caring for members of this committee at my medical office just a few blocks from here. It is a particular pleasure to speak before the subcommittee today. I have become deeply involved in managed care as an internist with numerous managed care affiliations and now as Medical Director of a local PPO.

In various articles, I have been critical of the performance of managed care, but nevertheless believe in the potential of organized delivery systems to provide the discipline necessary for cost control while preserving, and in the longer term, improving quality.

I endorse health delivery reformability about competing accountable health plans, and I believe a structured or managed system of competition is far preferable to the current dysfunctional markets in which patients and providers must function.

Once basic quality standards are guaranteed, perhaps throughout the type of uniform accreditation process others on the panel are talking about, the new system should permit consumers to choose the organized delivery system that best meet their needs. We should not be so prospective that all plans look alike, care for patients alike or even attempt to achieve the same health outcomes. I am concerned that the administration's proposal as drafted moves in that direction by overly restricting the autonomy and flexibility of plans to manage their own affairs.

Specifically, the point-of-service requirements interfere with the ability of organizations like HMO's to function. The concept of accountability for quality is meaningless when enrollees can move in and out of plans at will for services as basic as prevention and prenatal care.

In addition, health alliances appear to have too much authority to require plans to contract with particular providers. What starts with a very good case for some protections, such as for community health centers, may wind up down a slippery slope that leads to a supposedly market-based system that permits no losers. In this regard, any proposed changes to the antitrust laws should be carefully scrutinized. They should not be changed merely to protect providers from the effects of market competition.

When consumers, rather than employers, select health care plans with which to participate, I expect that quality will be a more important factor than it has been up to now in the managed care world. That is a reason to have a system of purchasing cooperatives or alliances that facilitate individuals selecting coverage from a broad array of insurance products.

To permit appropriate choices, I believe that we should require a great deal of disclosure from plans and avoid the paternalistic view that consumers do not know how to use information or that some of the information is too arcane for general understanding. Rest assured, that there will be a new industry of advisory services that will help the public understand how plans work and what the data means.



Consumers need basic information about the restrictions on seeing their preferred physicians, who they talk to in an emergency, the incentives that the doctors and other practitioners work under. For the most part, accurate and accessible information on these and other basic issues are not available today.

One of my duties on the White House task force that I participated on last spring was to co-chair the working group on malpractice reform. An idea some of us embraced was to shift malpractice to a system of enterprise liability, that is, holding plans liable for the negligent actions of their affiliated practitioners.

I learned very personally that the idea is apparently ahead of its time. Organized medicine certainly opposed the provision strongly. What was perhaps more interesting was the response from the managed care industry. The response essentially is that they have nothing to do with mistakes.

Health plans advertise that they have the most compassionate physicians, provide the highest quality, and use the most effective cost containment methods, but if something goes wrong, they had nothing to do with it. After all, they say medical care is provided by physicians, not health plans.

Emerging decisions suggest that courts will increasingly assign vicarious liability to plans for the negligent actions of their affiliated providers. Unfortunately, these decisions will emerge haphazardly, adding to provider plan and patient uncertainty.

Therefore, I believe the enterprise liability demonstration called for in the Health Security Act should go forward. Until we know more about formally shifting liability risk from providers to plans, we can nevertheless identify certain avoidable events—events that generally should not occur—as measures to be built into a quality report card.

In my opinion, managed care organizations are better able to monitor and improve substandard practitioner performance than underfunded and often uninterested State licensing boards. It is an activity for which we should hold plans accountable.

A challenge in health reform is to develop collaboration between managers and providers of care under the auspices of health plans to replace the adversarial relationships that exist too often today. I will just finish one sentence. Holding plans accountable for quality, not just cost containment, should lead health plan managers to realize that involving health professionals at all levels of decision-making is the best way to achieve quality.

Thank you.

Mr. WAXMAN. Thank you, Dr. Berenson.

[The prepared statement of Dr. Berenson follows:]

## TESTIMONY OF

ROBERT A. BERENSON, M.D.

MEDICAL DIRECTOR, NATIONAL CAPITAL PPO

I am Robert Berenson, M.D, and I am speaking on my own behalf today. I am medical director of the National Capital PPO and before my three month duty on the White House Task Force on Health Care Reform last year had been in private medical practice for twelve years as a general internist just a few blocks from here.

I have spent a lot of time on both sides of managed care, as a physician affiliated with numerous managed care plans and as a board member of an IPA-HMO and now of a PPO that I helped found. I believe in the potential of managed care and support the movement, endorsed by the Clinton Health Security Act, to the rapid development of organized delivery systems working with integrated medical practices.

In the short run, managed care organizations are well positioned to hold down health care cost inflation. In the long run, developing managed care organizations can produce more efficient and higher quality health care than a system based on independent and unaffiliated doctors and hospitals. Unaffiliated providers working on fee-for-service reimbursement was a good model when medicine mostly dealt with acute illnesses, such as infectious diseases. Increasingly, however, the health system is expected to care for patients with complex, chronic illnesses; to emphasize

prevention and education; and to take into account psychological and social determinants of illness and well-being. New forms of integrated practice, using teams of health professionals and modern communication technology, are better suited to these new challenges than independent practitioners, no matter how skilled and dedicated.

Managed competition, built on capitated payments to organized delivery systems, immediately solves certain problems resulting from fee for service incentives, such as documented excess utilization that results from self referral arrangements among providers. Unfortunately, capitation brings with it the concern of underservice, which occurred in the MediCal scandals of the 1970s. For the most part, the documented quality received in HMOs and PPOs is as good as in the traditional fee for service sector. However, that quality performance has been taken place mostly in noncompetitive markets where HMOs had plenty of room to do well financially while preserving prevailing standards of care. The concern, of course, is that managed care organizations will compromise on quality in the price-competitive markets envisioned in health reform.

That concern requires us to consider traditional quality assurance mechanisms to protect the public, including licensure of professionals and accreditation of organizations. And I support giving the public a guarantee that all competing health plans meet basic quality parameters as determined through an accreditation process.

However, markets need room for innovation and initiative. We should not be so prescriptive that all plans look alike, care for patients alike, or even achieve similar health outcomes. Once basic quality standards are guaranteed, by external oversight, the new system should permit consumers to choose the care delivery system that seems to best fit their needs. For some, getting higher perceived quality will be worth the extra cost.

In that regard, although I generally support the Clinton proposal, I think it that it overly restricts the autonomy and flexibility of health plans. Number one, the Administration plan gives the health purchasing alliances authority to require plans to contract with providers the alliance designates. What starts with a single compelling case for some protection, such as for Community Health Centers, may wind up down a slippery slope with a supposedly market-based system that permits no losers. In particular, the Committee should be vigilant that the antitrust laws not be changed merely to protect physicians and other providers from the effects of market competition, as recommended by many provider groups.

Number two, the Act's point of service requirements fundamentally interfere with the ability of organizations like HMOs to function properly and remain competitive. The concept of accountability for quality, the subject of today's hearing, is meaningless when enrollees can move in and out of a plan at will for services as basic as prevention and prenatal care.



I am confident that informed consumers will make the choices that well intentioned policy makers intend for them. When consumers, rather than employers, select the managed care plans in which to participate, I expect that quality will be a more important selection criterion than it has been up to now. Health plans will respond to consumer demand by contracting with those providers who have a standing in the community and the allegiance of their patients.

To permit consumers to make choices, I recommend that we require a great deal of disclosure from plans and avoid the paternalistic view that consumers do not know how to properly use good information. Although I applaud the efforts to generate outcome measures of quality, I believe that methodologic and other problems make realization of a comprehensive set of performance measures a goal that will take years to achieve.

From my experience, patients want to choose a health plan based on a few simple criteria, such as whether they can see their preferred physicians, and with what restrictions; whether they can select specialized facilities in unusual circumstances and with what restrictions; whether their personal physician is allowed the ability to give them the care they expect.

In current markets, for the most part, that kind of basic information is lacking or hard to decipher. For example, in my experience, plan brochures do not clarify the

restrictions on choice, e.g., precisely how the gatekeeper or case manager referral system works and who decides on access to specialists and specialized hospitals. Indeed, marketing materials tend to minimize restrictions, sometimes by listing all providers in the network, without specifying referral restrictions.

Moreover, I have studied physician payment policy in detail, as a researcher with the Urban Institute, as part of IPA and PPO management, and as an on-line primary care physician. I conclude there is no proper or improper way to compensate physicians. Salary, fee for service and capitation have their strong points and are also all subject to abuse which impacts on quality. Although I am concerned about capitation incentive systems that apply substantial risk to individual physicians and do not account for case mix differences or protect adequately against high cost cases, I would be reluctant to regulate such systems out. However, I am confident that many informed consumers would be reluctant to join a plan with this form of capitation and, in a well-functioning competitive system, would not have to.

As well, in the area of practice guidelines and coverage for controversial, experimental procedures, such as bone marrow transplantation for various forms of metastatic cancer, there is a need for a governmental role to establish broad parameters of acceptable practice or sometimes to actually make medical necessity decisions. However, the large majority of decisions on alternative approaches to diagnosis and treatment should be decentralized, made by plans in consultation with

the practitioners in their networks. Different plans likely will make different decisions on whether to use streptokinase or TPA for clot dissolving or when to use nonionic contrast for radiologic procedures. However, within reasonable bounds, these guidelines and coverage policies should be disclosed to the public and to providers prior to contracting.

Critics argue the details of this information are too arcane for the average consumer. Perhaps, for now. Nevertheless, I anticipate the rapid growth in consumer advisory services and personal health care advisors to make the information comprehensible and to offer recommendations. Over time, consumers will become as knowledgeable about how plans function as about particular health problems with which they have an interest. Disclosure requirements should be comprehensive and monitored to assure compliance.

One of my duties on the Health Care Task Force was to co-chair the working group on malpractice reform. An idea some of us embraced was to shift to a system of enterprise liability, that is, holding plans liable for the negligent actions of their affiliated providers. This idea is apparently one that is ahead of its time and was subject to concerted criticism from organized medicine and many in the managed care industry. Physicians were concerned about the perceived loss of their autonomy and professionalism. Apparently, they want to be named personally in law suits. The

managed care response is that they have nothing to do with mistakes. Health plans advertise and market that they have the most compassionate physicians, provide the highest quality, and use the most effective cost containment mechanisms, but if something goes wrong, they have nothing to do with it-- after all, medical care is provided by physicians, not health plans. It seems to me they cannot have it both ways.

Emerging decisions suggest courts will increasingly assign vicarious liability to plans for the negligent actions of their affiliated providers. Unfortunately, these court actions will likely occur haphazardly and inconsistently. It is preferable for plans to have formal liability-- whether jointly with providers or solely-- so that they would have to balance the competing claims for cost containment, quality enhancement and risk management. The result should be more consistent and coherent approaches regarding clinical policies and practitioner oversight.

I strongly urge that the enterprise liability demonstration program in the Health Security Act go forward. Until we know more about formally shifting liability risk from providers to plans, we can identify certain avoidable events-- outcomes that should not happen-- as measures to be built into a quality "report card." I support the shift in quality improvement from the punitive targeting of bad doctors to a cooperative, group endeavor that seeks to improve the overall quality of the health organization, so-called Total Quality Improvement. However, I doubt TQI tolerates



substandard performance by members of the organization. In my opinion, managed care organizations are better able to monitor and improve substandard practitioner performance than under-funded and often uninterested state licensing boards. It is an activity for which we should hold plans accountable.

A challenge in health reform is to develop collaboration between managers and providers of care under the aegis of health plans to replace the adversarial relationships that too often take place today. Holding plans accountable for quality, not just cost containment, should lead health plan managers to recognize that involving health professionals at all levels policy-making is the best way to achieve high quality. Consumers need information about all aspects of plan operations, not just particular quality measures. I am confident that with this information, they will choose quality.

Mr. WAXMAN. Chairman O'Leary?

# STATEMENT OF DENNIS O'LEARY

Mr. O'LEARY. Thank you, Mr. Chairman.

We appreciate this opportunity to provide you with our perspective on the adequacy of the Health Security Act's provisions for assuring quality in a managed care environment.

The Joint Commission evaluates and accredits more than 9,000 health care organizations, including 80 percent of U.S. hospitals. We have also previously set standards for and accredited managed care organizations. And in 1994, we will initiate an accreditation program for the type of integrated health care networks contemplated under the Health Security Act. On the basis of our experience, we feel well qualified to address the issues at hand.

We commend the President for proposing an important new quality framework to undergird his health care reform proposal. The bill would establish a national system for gathering and disseminating performance information about health plans in the form of report cards to support informed decision-making by consumers. The availability of information on specified quality parameters would also give plans the ability to use this information in their internal quality improvement activities.

Notwithstanding our general support for the quality management and improvement section of the bill, we are concerned that the architecture laid out in the President's bill will not effectively support the goals most of us hold for a meaningful quality oversight system. We suggest certain modifications to the bill's quality program to strengthen its oversight potential, to sustain public confidence in the new delivery system, and to promote continuous improvement in the delivery of health care services.

First, we urge the Congress to expand the concept of report cards to require the establishment of state-of-the-art national quality standards for health plans as an integral feature of health care reform legislation.

We draw your attention to the bill's omission of any Federal intent to establish and apply quality standards for health plans. Rather, it appears that States would be permitted to choose any method they desire for certifying health plans for quality without any guidance from the national council.

Standards are critical because they are the sole type of measure capable of influencing and predicting future performance of provider organizations, including health plans. As such, they are an important complement to outcomes and other types of performance measures which quantify what has occurred in the past. Absent the creation and use of standards, the achievement of desired patient outcomes, in essence, becomes a dice roll.

Performance measures of the type currently being viewed as the primary substrate for report cards are also a significant component of the quality oversight process. But used alone, they do have inherent limitations. First, the number of specific measures that could be included on a report card, 50 in the Health Security Act, is quite small in proportion to the number of measures of potential interest to consumers. By contrast, standards compliance offers as-

surances with respect to a much larger number of important variables.

Second, most current performance measures developed for health plans focus on process and access issues and few on clinical or functional outcomes. Therefore, on-site evaluation of health plans against relevant standards is essential to obtaining a full picture of a plan's potential for delivering high quality care.

Third, there is no reliable basis for simply extrapolating the past achievement of good outcomes by a health plan into the future. The past achievement of good outcomes usually means that the health plan was in compliance with relevant standards; that is, the plan was doing right things right.

Extrapolation to expectations of good outcomes in the future requires of necessity that the health plans continue to be in compliance with relevant standards.

Our second recommendation is we urge the Congress to assign to the Federal Government the responsibility for standardizing the quality measures to be used in quality oversight programs for health plans.

We make the obvious observation that good measurement is a sensitive process, and a range of important decisions and judgments will be based on the resulting performance information.

Standardization of the standards and the performance measures to be used in evaluating health plans is a unique and vital Federal role. If there is no Federal effort to standardize the measures, there will, in essence, be 50 different quality programs. This will subvert the interests of multistate employers who will wish to compare provider performance across States, multistate providers who will be held to disparate and potentially conflicting requirements across the States in which they provide care, and individual consumers who, sometimes of necessity, shop across State lines for health care and will have, instead of useful report cards, a meaningless polyglot of performance information.

In closing, I reiterate that the most crucial role in developing a quality Federal oversight program is standardization of the measurement system. I will stop at that point.

Mr. WAXMAN. You could say a concluding sentence. Thank you very much.

[Testimony resumes on p. 461.]

[The prepared statement of Mr. O'Leary follows:]



*Joint Commission*  
on Accreditation of Healthcare Organizations

STATEMENT OF THE  
JOINT COMMISSION ON THE ACCREDITATION OF HEALTHCARE  
ORGANIZATIONS

to the  
Subcommittee on Health and the Environment  
HOUSE ENERGY AND COMMERCE COMMITTEE  
presented by

DENNIS S. O'LEARY, M.D.

PRESIDENT

February 3, 1994

Chairman Waxman, and members of the Subcommittee, we appreciate this opportunity to appear before the Subcommittee to respond to issues of quality measurement under a reformed health care system. We understand that the Subcommittee is charged with assessing the quality section of the Administration's bill, the Health Security Act, and that you are seeking advice as to the bill's adequacy for assuring quality in a managed care environment.

The Joint Commission evaluates and accredits more than 9000 health care organizations, including 80% of U.S. hospitals. As such, we are uniquely qualified to speak to these issues. Our stated mission is to improve the quality of health care - -



ultimately reflected in positive patient outcomes - - by measuring and evaluating performance and stimulating needed change in health care organizations.

We commend the President for proposing an important new quality framework to undergird his health care reform proposal. This framework is built on the premise that consumers can effectively leverage the purchasing power of their dollars when provided with useful and understandable information on quality.

To accomplish quality oversight, the bill would establish a national system for gathering and disseminating performance information. This would require routine submission of data from all health plans. A new National Quality Management Council would select the measures to be monitored. The data would be incorporated into Report Cards made available annually to the public. It is anticipated that selected performance data on individual health care organizations and practitioners would eventually be part of these Report Cards, but only when the data are statistically meaningful. It is important to note, however, that all Report Card information would derive from self-reported data.

We applaud the focus on gathering and using performance information to support informed decision-making in health care. Such information is integral, as well, to the infrastructure of sound quality management and would encourage the application of well-established industrial concepts to constructive oversight of the health care system. The availability of standardized

information on specific quality parameters would give plans the ability to compare their performance with others and use this information in their internal quality improvement activities. Indeed, measurement is necessary to identify and guide opportunities for improvement, and to confirm that changes made were really improvements.

This framework closely tracks the principles embodied in the Joint Commission's Agenda for Change, which have recently framed a comprehensive modernization of our accreditation process. The criteria for selecting Report Card performance measures is similar to the design of the Joint Commission's new IMSystem which will continuously collect objective data on indicators of important governance, managerial, clinical and support functions of each accredited organization. Indicators will be used to stimulate improvement in these organizational functions. Additional information on the Agenda for Change appears in the appendix to this testimony.

Notwithstanding our general support for the Quality Management and Improvement section of the bill, we are concerned that the architecture laid out in the President's bill will not support the goals most of us hold for an effective quality measurement system. We suggest certain modifications to the bill's quality program to strengthen its oversight potential, maintain public confidence in the new delivery system, and promote continuous improvement in the delivery of health care services.

First, we urge the Congress to expand the concept of Report Cards to include reporting on each health plan's compliance with state-of-the-art, federal standards. We believe that the most crucial federal role in developing a quality oversight program is standardization of a meaningful national measurement system. At the least, this will require a carefully constructed, single set of measures that assess both past performance (performance measures) and standards which gauge future potential.

In this regard, we draw the Subcommittee's attention to the bill's omission of any federal program for the establishment and application of quality standards for health plans. In fact, it appears that states would be permitted to choose any method of certifying health plans for quality, without any guidance from the National Council as to what constitutes a reasonable certification program or what a reasonable core set of standards should be.

We submit that the omission of federal standards is an error that could lead to both an erosion of public confidence in the system and insufficient evidence upon which to judge the effects of health care reform on quality of care.

Standards are critical because they are the sole type of measure capable of influencing and predicting future performance of provider organizations, including health plans. As such, they are an important complement to outcomes and other types of performance measures.

Standards articulate performance expectations. Compliance

with such standards introduces a favorable bias into patient outcomes, and thus into measures that reflect these outcomes. That is, if a health plan is doing well what it is supposed to do, such as providing timely access to patients with acute illnesses, this will significantly increase the likelihood of good patient outcomes, as reflected in performance measures. Absent the creation and use of standards, the achievement of desired patient outcomes in essence becomes a dice roll.

Performance measures, too, have an important role in this new oversight process. At the same time, it is important to recognize that these measures do have inherent limitations:

- + Report Cards containing only performance measures would quantify the performance of a health care organization on the relatively small number (approximately 50) of important variables that would be measured. Standards compliance offers assurances with respect to a much larger number of variables.
- + Performance measures reflect only past performance and do not predict the future performance of the organizations which the consumer-turned-patient must choose among for care.
- + Further, most current performance measures for health plans focus on process and access issues, and few on clinical or functional outcomes. With respect to the anticipated Report Cards, this is unlikely to change in the near term. Therefore, on-site evaluation of health



plans against relevant standards is essential to obtaining a full picture of a plan's potential for delivering high quality care.

- + Lastly, performance measures are usually self-reported data. We raise the caution that such data are easily misreported and sometimes purposefully engineered to reflect favorable performance. Such propensities can be curtailed through on-site evaluations and other screening mechanisms.

Developing meaningful standards for health plans presents a more complex and unusual challenge than does the process for creating, say, home care standards. For example, the standards for health care networks that the Joint Commission has recently developed recognize that there are certain important dimensions of quality peculiar to the complex configurations of care that will characterize tomorrow's health plans. For instance, standards will need to assess factors that relate to the integration of services and their accountability. These include attention to continuity of services, access to and use of patient care information, and health plan management, among others.

We should expect state-of-the-art, quality-related performance objectives or standards from our National Quality Management Council. Absent such a requirement, there will in essence be 50 different quality programs. This will subvert the interests of multi-state employers who will wish to compare provider performance across states; multi-state providers who

will be held to disparate and potentially conflicting requirements across the states in which they provide care; and individual consumers who, sometimes of necessity, shop across state lines for health care and will have, instead of useful Report Cards, a meaningless polyglot of performance information.

Beyond concerns about the potential impossibility of any meaningful performance comparisons between or among states, Congress will lack sufficient national, comparable data on health plans to judge the effects that health care reform has had on quality. Without national standards, the information necessary to respond to public concerns about the impact of health care reform on quality will not be available. We should all be reminded that continuing public confidence is fundamental to the success of health care reform.

Our second suggestion is that the National Quality Management Council be expanded, or simply be required to include representation from those having expertise in direct quality evaluation. Such expertise is important to the creation of an efficient and sound system of performance measurement. We have considerable experience with the complexities of implementing national systems of quality evaluation and monitoring, and we understand the technical issues and difficulties that attend such a formidable undertaking.

One of the major challenges such a Council would face is selecting and refining measures that will produce useful performance information across plans. Comparable, risk-adjusted,

accurate and understandable information is the critical linchpin to the successful use of Report Cards by consumers. Such high quality information will also be essential if we are to expect providers of care to take the Report Cards seriously and commit themselves to improvement on these measures.

It is also important that experienced persons with the right type of expertise sit on the Council, because the Council would be involved -- through legislative reference -- in the data activities that are part of the bill's information section. The tasks of identifying appropriate performance measures that truly reflect significant patient outcomes; testing these measures for validity and reliability; and developing data specifications to ensure comparability of findings, dictate that organizations with this experience be part of the National Quality Management Council.

I want to emphasize the willingness of the private sector to assist the federal government in these nascent efforts to develop effective Report Cards for consumers. The Joint Commission is firmly on record in support of providing useful information about provider performance to the public. Private sector accrediting bodies represent a vital resource in helping the federal government standardize the measurement framework and tools that will underlie the anticipated consumer Report Cards.

In closing, I reiterate that the most crucial federal role in developing a quality oversight program is standardization of the measurement system. With so massive a contemplated change to

the health care delivery system, the federal government will have at least a moral obligation to assure effective oversight of the quality of care being provided. Within this obligation lies a minimum requirement to establish a national, uniform system of standards and performance measures. In that way, confusion will be minimized, comparisons between and among providers will be valid, and consumers and Congress may confidently rely on the data.

The Health Security Act provides a sound framework for building the best quality measurement system in the world, and to enhance -- not just maintain -- the level of quality that Americans expect. We should seize this opportunity.



## APPENDIX

We provide the following information to the Subcommittee by way of indicating the capability of the Joint Commission to support the federal government in its nascent efforts to foster effective measurement activities and to create useful Report Cards for consumers:

The Joint Commission is the nation's oldest and largest health care standards-setting and accrediting body and is the recognized national leader in developing standards and performance measures for health care organizations. It is a private, not-for-profit organization governed by a 28-member Board of Commissioners that includes professional and provider organization representatives and six public members. For more than 75 years, the Joint Commission and its predecessor organization have been dedicated solely to measuring, evaluating, and improving the quality of health care services provided to the public.

For over a quarter century, the federal government has relied upon Joint Commission accreditation to certify health care facilities as eligible to receive Medicare and Medicaid payments. In the landmark Social Security Amendments of 1966 -- better known as the Medicare Act -- Congress embraced a partnership between the private sector and the federal government to set and apply minimum quality standards. This partnership, since altered and strengthened, has served as the basis for the evaluation and

certification of thousands of hospitals and other healthcare organizations since 1965. It is generally agreed that this arrangement has contributed significantly to progressive increases in the quality of care in the United States over time, thus supporting the interests of consumers, providers, purchasers, and the federal government alike.

Additionally, forty two states and the District of Columbia have woven Joint Commission accreditation into their mechanism for health care facility licensure purposes, and many health care insurance companies consider Joint Commission accreditation in making reimbursement decisions. Moreover, a variety of other private sector, federal and international entities continue to turn to the Joint Commission for direction in guiding health care quality improvement initiatives.

As a nationally known and respected evaluator of health care organizations, the Joint Commission is in a unique position to develop comprehensive and objective systems for assessing health care delivery and patient outcomes against quality measures. In this vein, it has frequently taken a leadership role in formulating the content of quality measurement approaches and tools, and in embracing principles of continuous quality improvement. For example, the Joint Commission began its work on performance measures, or indicators, in the mid 1980's. It also prepared the first accreditation manual for managed care organizations, and now has developed the first set of performance objectives for integrated networks of care (a.k.a. health plans.)

*AGENDA FOR CHANGE*

In 1986, the Joint Commission began its Agenda for Change, which encompasses the total recasting of Joint Commission standards to focus on performance and the development of a new outcomes-based measurement system, called the Indicator Measurement System, or IMSystem. Both of these measurement approaches place primary emphasis on the clinical care provided directly to patients and the management of the health care organization being evaluated. This long-planned transition in the Joint Commission's accreditation process is now being implemented, and is more fully described in the attached materials that are submitted for the record.

Three major goals for the Agenda for Change were established:

1. To direct primary attention to the patient and his or her care;
2. To focus attention as well on organizational systems management;
3. To emphasize performance over capability in both of these areas.

To serve these overall goals, the Agenda for Change has consisted of three major initiatives: (1) to recast and refine the accreditation standards to accent performance and incorporate continuous improvement concepts; (2) to increase the relevance and precision of the accreditation survey process; and (3) to

create a system to continuously monitor organization performance that will include a national reference database (IMSystem). And to support the implementation of these initiatives, the the Joint Commission has adopted a full disclosure policy that will make organization-specific standards compliance and other performance information available to the public for the first time.

The IMSystem will be implemented on a voluntary basis in 1994 with 10 fully-tested indicators. There will be 20 indicators by 1995, and 30 in 1996 when it is anticipated that the indicator measurement system could become integrated into the accreditation decisionmaking process. An "indicator" is a quantitative measure used to measure and improve performance and quality. It is expected that indicators will be used by organizations to continuously monitor, evaluate and improve patient care.

#### *HEALTH CARE NETWORK EVALUATION AND ACCREDITATION PROGRAM*

In addition to fundamental changes in its measurement approaches, the Joint Commission has recognized that integrated health care networks, or health plans, are increasing in number and are a prominent feature of the reform landscape. In response, we have been actively developing an evaluation and accreditation program tailored to the characteristics of these new entities. This new program is to be launched this Spring. A pioneering venture, it will initially include standards and eventually performance measures applicable to networks and their subset parts, such as hospitals and home care agencies. We



believe this program can be immensely valuable to states wishing to collect performance information across their evolving delivery systems and to compare this information with the network experience in other states.

The proposed standards were reviewed and approved by the Board of Commissioners at its January 1994 meeting. Prior to that action, the standards had been reviewed by a wide spectrum of experts and by a national Network Advisory Committee which is providing technical guidance in developing and implementing the network evaluation and accreditation program. The standards are designed to measure quality while stimulating improvement within the health plan. The standards emphasize issues related to network-wide integration, coordination, and accountability, and address such areas as Patient Rights; Organization Ethics; Continuum of Care; Communication; Leadership; Utilization Management; Human Resources Management; Performance Improvement; Information Management; and Consumer Education.

Mr. WAXMAN. Ms. Dallek, we are pleased to have you from Los Angeles.

# STATEMENT OF GERALDINE DALLEK

Ms. DALLEK. Thank you very much.

I am the Executive Director of the nonprofit Los Angeles based Center for Health Care Rights. We were recently a former Medicare advocacy project. We just changed our name.

In January 1993, the center published the results of a year long study on Medicare risk-contract HMO's. This testimony is based on the study's findings and on my program's work with thousands of Medicare beneficiaries enrolled in HMO's, and I would like to give the executive summary of our finding—of our study to be put in the record.

Mr. WAXMAN. Without objection.

Ms. DALLEK. Our program applauds the president's all-out effort to reform the health care system, however, we believe that additional quality of care protections are badly needed in the plan.

Number one, we need from CHAP greater specificity on State monitoring responsibilities and enforcement powers. The Health Security Act gives States the authority to certify and monitor plans but provides absolutely no guidance to States on either certification criteria or monitoring requirements.

Most States do not currently have the expertise to protect consumers in a managed care environment, and I think California is a case in point. California has had a great deal of experience with HMO's and yet our State oversight authority that rests with the Department of Corporations is really quite poor. We need to have much stronger State monitoring authority.

The Health Security Act is also silent on State authority to require plans to meet minimal quality of care standards or to take necessary corrective action to address problem areas. For example, what authority would a State have if it determined that a certified plan has an excessive number of justified complaints and grievances filed against it or has not met marketing guidelines? We have had a lot of problems with HMO marketing in Los Angeles for the Medicare population.

The Health Security Act should establish national criteria for plan certification as well as standards for State monitoring. Otherwise, we will have a hodgepodge of State rules and the quality of care will depend on which State you live in, not on anything else.

State flexibility is great. I am all for it. It sounds wonderful but not at the expense of consumer protections.

Number two, we do need an establishment of an external independent quality review entity, and I think it is very important. Several of the other panel members have also raised that point.

You measure quality in a number of ways, looking at structure, process, and outcome. Outcome data is not enough. We need an outside external monitoring agency and entity that is independent to look at the process of care, what goes on in these plans, because we see a lot of subtle underservice for the Medicare population.

We are often unable, or our clients are unable, to get home health care, rehab services, a whole range of services. Oftentimes, this is not black and white. It is gray. But I am absolutely con-

vinced given the experience we have with our HMO Medicare clients that there is real underservice going on there, and we need some good data to take a look at that.

Three, the need for adequate quality protections for the Medicare population. Basically the Clinton plan allows States at their will to integrate Medicare, but most States would not do so, would probably wait. The Clinton plan proposes elimination of the PRO system but with nothing to stand in its place.

We need to strengthen monitoring of Medicare HMO's to protect the Medicare population. They are inadequately protected now. We don't need to weaken and eliminate what little protections we have, and my written testimony has a great number of suggestions on what we need to do in terms of strengthening quality protections for the Medicare program, but we would oppose the elimination of PRO's without some really good monitoring in its place.

We need additional consumer protections against underservice. We know little about the relationship between financial risk and managed care plans, who is at risk, for how much and for what services and quality of care. Sometimes we find that it is not the plan that is the problem; it is the subcontracting medical groups. A plan might subcontract with a zillion different medical groups. We have no problem with medical group "A," but medical group "B," we are getting lots and lots of complaints from. So it really is critical to understand how much risk individual physicians and medical groups are put at.

The General Accounting Office, as we learned on several occasions, that placing too much financial risk on either managed care plans or contracting provider groups is a recipe for disaster. To protect consumers against a plan to underserve, Congress should limit the risk of individual providers and provider groups, strengthen due process and marketing protections and retain the requirement that all managed care plans offer a point-of-service option for enrollees.

I strongly disagree with Dr. Berenson, is it, because I think point-of-service plans are critical for any HMO enrollees to get outside second opinions in terms of the care that is being provided. We also need a great deal more information in terms of consumer quality of care information.

I want to thank you very much for having me here.

Mr. WAXMAN. Thank you very much for your testimony.

[Testimony resumes on p. 511.]

[The prepared statement of Ms. Dallek follows:]

## STATEMENT OF GERALDINE DALLEK

**INTRODUCTION**

My name is Geraldine Dallek and I am the executive director of the Center for Health Care Rights (formerly the Medicare Advocacy Project). I appreciate the opportunity to testify on quality assurance in the Clinton plan.

The Center for Health Care Rights (CHCR) is a Los Angeles-based independent non-profit organization dedicated to ensuring that consumers obtain the medical care services to which they are entitled. Through its state HICAP grant, CHCR provides direct counseling and legal assistance to over 5,000 Medicare beneficiaries annually. In addition, CHCR works for health care reform through class action litigation and research.

In January 1993, CHCR published the results of a year long study on quality of care, due process and marketing issues in Medicare risk-contract HMOs. This testimony is based on the study's findings and on my program's work with thousands of Medicare beneficiaries enrolled in HMOs.

Numerous studies have found that managed care plans, such as health maintenance organizations (HMOs), can and do provide high quality care to enrollees. Other studies, however, raise serious concerns about the incentives inherent in these plans to underserve enrollees. To counter these incentives, the Health Security Act needs stronger quality assurance protections.

The Health Security Act does contain a number of critical quality measures, the most important of which are the collection and dissemination of quality outcome measures in a plan "report card" and the development of practice guidelines. However, these measures are insufficient to protect consumers for the following reasons:

- Managed Care plans are not required to collect and make public basic quality of care information;
- Data collection/analysis requirements in the Health Security Act are inadequate to protect consumers from underservice;
- Most states do not currently have the expertise to protect consumers in a managed competition environment;
- The Health Security Act lacks specificity on state options to address quality of care problems;
- The Health Security Act does not provide for an independent organization to monitor the quality of care provided by managed care plans;
- The Health Security Act does not address key issues of the financial risk of managed care plans and their contracting medical groups; and



- The Health Security Act does not contain adequate quality protections for the Medicare population.

Each of these issues is addressed separately below. In addition this testimony includes a brief discussion of CHCR's concerns with the lack of adequate consumer due process and marketing protections in the Health Security Act.

# **I. MANAGED CARE PLANS ARE NOT REQUIRED TO COLLECT AND MAKE PUBLIC BASIC QUALITY OF CARE INFORMATION.**

## **Background**

The provision of quality of care data in a consumer-friendly format is basic to the entire notion of managed competition. The most common question asked by individuals considering whether to join an HMO is "which one is best." Currently, people are forced to make a very critical decision about their health care in a total information vacuum. Unfortunately, as discussed below, neither the federal government nor states require plans to provide any meaningful quality of care data, and plans do not do so.

The Health Care Financing Administration (HCFA) and state governments have been extremely lax about HMO data collection in both the Medicare and Medicaid programs. HCFA, for example, collects, but does not analyze Medicare HMO disenrollment data, collects no meaningful utilization or outcome data by plan, and has very loose standards for defining (much less investigating or keeping data regarding) types of complaints received. In short, HCFA collects and provides to the public no usable quality of care data.

The states are no better at data collection. Very little useful data is available from state agencies on managed care plans serving the Medicaid population. And, what data is available is often kept hidden from consumer representatives. For example, CHCR and the National Health Law Program have been trying for almost six months to obtain HMO Medicaid data from the state that, by law, is public information.

Although some HMOs have sophisticated data collection systems, most refuse to provide any quality of care information to consumers, claiming that it is "proprietary." Even worse, many managed care plans are unable to provide rudimentary information to oversight agencies. For example, when California's Peer Review Organization requested patient records on a randomly selected number of Medicare HMO enrollees, some HMOs could not even determine to which subcontracting medical group their enrollees belonged and, thus, could not find the requested medical records.

Finally, the little data available to consumers is of questionable value. A number of states have adopted the National Association of Insurance Commissioners' "model"

HMO law which requires HMOs to provide gross hospital and physician utilization data. However, when CHCR looked at the HMO utilization data sent to the California Department of Corporations (the California agency with HMO oversight responsibility), it found that reporting inconsistencies made the data worthless. Compounding the problem, the Department of Corporations (DOC) has made no attempt to check on the reliability and validity of the data reported to it.

### **Recommendations**

In order to protect consumers from poor quality plans and to ensure that managed care plans can meet the reporting mandates of the Health Security Act, Congress should require HCFA and the states to:

- Strengthen immediately HMO quality of care reporting requirements for Medicare, Medicaid and all federally-qualified HMOs; and
- Make available to the public appropriate quality of care data.

## **II. DATA COLLECTION AND ANALYSIS REQUIREMENTS IN THE HEALTH SECURITY ACT ARE INADEQUATE TO PROTECT CONSUMERS FROM UNDERSERVICE**

### **Background**

The Health Security Act should require more specific data to be collected and analyzed. The Clinton plan's proposal for the publication of plan outcome measures in a "report card" format is an excellent first step towards ensuring that health care consumers obtain quality of care information and high quality care. However, for such a report card to be useful and effective in allowing consumers to compare plans, additional plan-specific and condition-specific information must be collected and made public.

Without this data, states and alliances will be unable to adequately protect consumers from potential underservice. For example, CHCR's Medicare HMO study included an analysis of HMO hospital utilization data obtained from California's PRO. This analysis found a significant difference in hospitalization rates for specific DRGs -- including a six-fold difference in the rates of heart bypass surgery -- among the three largest Medicare risk-contract HMOs in California. Because of questions about the accuracy of hospital HMO utilization data, CHCR recommended that HCFA strengthen its enforcement hospital reporting requirements. Instead, HCFA notified the PROs that, because the data might be flawed, they were not to use it. This was the wrong response! If a six-fold

difference in bypass surgeries exists, it needs to be investigated, not ignored.

As another example, a recent study by Mathematica (1993) found that Medicare HMO enrollees received 50 percent less home health visits than Medicare fee-for-service beneficiaries. In CHCR's HMO study (1993), the large majority of hospital discharge planners, home health providers and rehabilitation providers surveyed noted that it was difficult to obtain needed care from certain HMOs and contracting medical groups. They reported that HMOs' referral and utilization control systems were used to delay and to deny needed care.

One of my staff was told by an HMO employee that the HMO does not provide home health aide services, even though it is required by law to do so. Another HMO recently told a referring hospital employee that the HMO would not provide a needed hip replacement to one of its enrollees because the HMO had filled up its "hip replacement quota this year."

Basic utilization data, adjusted by age, sex and, whenever possible, health status, is needed to assess whether managed care plans systematically deny certain types of services.

### **Recommendations**

CHCR is a member of the Coalition for Consumer Protection and Quality in Health Care Reform, a coalition of more than 25 consumer groups, which testified before this committee earlier in the week. CHCR supports the Coalition's recommendations that the Health Security Act require the collection, analysis and reporting of additional quality of care data, including:

#### **Comparative Information**

- Results of consumer satisfaction surveys;
- Plan enrollment and disenrollment figures;
- The ratio of complaints/grievances and appeals to plan enrollees;
- Information on plan providers and costs of out-of-plan use;
- Ratio of primary care practitioners to enrollees and the ratio of board certified to non-board certified physicians;
- Information on plan benefits and any limitations on these benefits;
- Individual plan risk-arrangements (financial incentives under which plan health care providers operate); and
- Plan utilization data for selected services, including hospitalization, home health visits, and psychiatric visits adjusted for age, sex and, when possible, health status.

### **Plan-Specific Information**

- Fact sheets on each plan physician--their training, years of practice, board certification, faculty responsibilities, and confirmed disciplinary actions such as repeated malpractice payments; and
- On request, fact sheets on individual hospitals, home health agencies, laboratories, pharmacies and other contracting providers with list of services and other details.

### **Condition-Specific Information**

- Number of surgeries performed (by hospital and by surgeon);
- Death rates within a specified time period;
- Complication rates for specified surgeries (e.g., surgery for prostate cancer); and
- hospital infection rates (generally) and readmissions for the same condition within a specified time period.

### **Point-of-Service Option**

The provision of additional information is not enough to protect HMO enrollees in enrolled in plans that provider poor quality of care. The Health Security Act permits consumers to switch plans only once a year. Therefore, it is critical that managed care enrollees retain the option of seeking care outside a managed care plan. Specifically, the CHCR strongly recommends that:

- The Health Security Act's requirement that HMOs offer a "point-of-service option" be retained.

## **III. MOST STATES DO NOT CURRENTLY HAVE THE EXPERTISE TO PROTECT CONSUMERS IN A MANAGED CARE ENVIRONMENT**

### **Background**

The Health Security Act requires states to establish health plan certification criteria relating to quality, financial stability, and capacity of a plan to deliver the comprehensive package of services in a designated area, as well as to certify and monitor plans. However, the Act provides no guidance to states on the certification criteria or monitoring activities. For example, the Act's only guidance to states on monitoring activities is the following:

"A participating State shall monitor the performance of each State-certified regional alliance health plan to ensure that it continues to meet the criteria



for certification." (§1203(c))

Unfortunately, states are currently in no position to assume the certification and monitoring functions envisioned by the Act. The history of Medicaid HMOs is replete with states' failures to adequately monitor HMOs caring for the poor. Take California, for example. After reviewing California's administration of its Medicaid Managed Care program in 1993, HCFA Region IX found that the state's managed care "administrative machinery is in need of a major facelift," and that "rapid expansion of Medi-Cal's managed care component would be counterproductive and ill advised." (HCFA, 1993).

Nor does California, where the large majority of residents are enrolled in some type of managed care plan, adequately monitor HMOs serving the entire population. The responsibility for licensing and monitoring California HMOs rests with the Department of Corporations (DOC). A 1992 study by the California Auditor General found that DOC does not effectively manage its medical surveys, does not release its survey reports in a timely fashion, ineffectively follows up on problems and does not process enrollee complaints in a timely manner (CA Auditor General, 1992). Moreover, DOC monitors state HMOs only once every five years, and collects no usable quality of care data (CHCR, 1993).

The General Accounting Office has found wide variations in the resources, staff and effectiveness of state Departments of Insurance (which, in most states, regulates and monitors managed care plans). The GAO was particularly concerned that many states do not adequately monitor insurer financial solvency. For example, only six states have adopted the National Association of Insurance Commissioners' model on HMO investments, which sets limits on HMO investments to protect against solvency problems (GAO, 1993).

Managed care plans are spreading like wildfire throughout the country. Nevertheless, some states have few or no HMOs and, thus, have little or no expertise in monitoring these entities.

Finally, the Health Security Act is so vague about state certification and monitoring requirements that we are likely to see wide variations in state monitoring and enforcement authority, resulting in inadequate consumer protections in many states.

### Recommendations

- The Health Security Act should set minimum national standards which states must follow in their certification and monitoring functions.
- The Health Security Act should provide training for states agencies with managed care oversight authority.

#### **IV. THE HEALTH SECURITY ACT LACKS SPECIFICITY ON STATE OPTIONS TO ADDRESS QUALITY OF CARE PROBLEMS**

Currently, the federal and state governments lack adequate authority to require managed care plans to take corrective action to ensure that plans meet minimum beneficiary safeguard standards.

In the Medicare program, HCFA is years late in issuing intermediate sanction regulations enabling the agency to impose appropriate penalties for Medicare HMOs that do not correct marketing or quality of care problems. Short of freezing new enrollments or terminating the contract, the agency has little authority to force HMO compliance with its regulations.

Similarly, the Health Security Act is silent on state authority to require plans to meet minimum quality of care standards or take necessary corrective actions. For example, what authority would a state have if it determines that a certified plan has an excessive number of justified complaints and grievances filed against it, has not met state marketing guidelines, or has failed to provide accurate data to the alliances? States need authority to enforce, short of decertification, compliance with state consumer quality of care protections.

#### **Recommendation**

- The Health Security Act should specify a range of penalties (including monetary penalties) states can impose on certified plans for failure to meet state quality of care standards.

#### **V. THE HEALTH SECURITY ACT DOES NOT PROVIDE FOR AN INDEPENDENT ORGANIZATION TO MONITOR THE QUALITY OF CARE PROVIDED BY MANAGED CARE PLANS**

The Health Security Act provides an excellent foundation for independent monitoring of quality through the establishment and functions of the National Health Board, National Quality Management Program, and the National Quality Management Council at the federal level and the alliance quality of care reporting requirements at the state and local level. However, the Clinton plan does not include the establishment of consumer-based independent entities to monitor and improve the quality of care provided by plans.

Quality of health care should be measured in three ways: structure; process; and outcome. All three complement each other and are needed if we are to adequately protect consumers in a managed care environment. The Clinton plan does provide for information on outcome measures, but as discussed above, provides no guidance to

states on certification criteria relating to plan structure. Moreover, the Health Security Act does not require any monitoring of the process of care.

Many managed competition advocates believe that providing managed care enrollees with cost and quality information (through a report card) is enough to protect consumers and to force plans to provide high quality care. The buyers of health care (consumers) who are unhappy with a particular plan can simply "vote with their feet," by changing plans. Unfortunately, experience with managed care plans shows that this ideal system bears little resemblance to the real world of managed care.

CHCR and other consumer advocates have seen too many problems with underservice in managed care plans to believe that simply providing outcome information and establishing practice protocols will adequately counter financial incentives to underserve and will adequately protect the most vulnerable populations.

### **Recommendations**

The Clinton proposal should include an external quality review entity, independent of the payer-based alliances and provider-based plans, to monitor and improve quality in each state. These entities would perform a variety of quality monitoring and improvement functions, including:

- Performance of expedited quality of care reviews (see below);
- Data analysis and data quality testing;
- Dissemination of information on successful quality improvement programs;
- Technical assistance to plans and alliances;
- Development of, and support for, quality improvement activities;
- Provision of consumer information beyond the report card;
- Monitoring and feedback to plans on adherence to practice guidelines;
- Data base analysis of plan utilization measures; and
- Quality assurance by providing:
  - information to consumers
  - feedback to licensing, certification, and accrediting entities and the National Quality Management Council for appropriate sanctions.

## **VI. THE CLINTON PLAN DOES NOT CONTAIN ADEQUATE QUALITY PROTECTIONS FOR THE MEDICARE POPULATION**

The Health Security Act proposes the termination of Medicare Peer Review Organizations. Although I believe that the mandate and functions of these organizations should be strengthened, I oppose their elimination.

Under the Clinton proposal, states have the option of "integrating Medicare" into

the Alliance system. Most states will likely keep Medicare separate initially, until they can assess how well the new program is working. If Medicare remains separate, it will not be covered by any of quality protections in the Health Security Act. It makes no sense to eliminate PROs without a new program to monitor Medicare quality of care. We need stronger, not weaker, quality of care protections for Medicare beneficiaries, especially those enrolled in HMOs.

### **Recommendations**

- As long as Medicare remains a separate program, Congress should continue PRO funding;
- Congress should strengthen PRO Medicare HMO quality of care oversight functions, including increased data collection and analysis and elimination of draconian restrictions on the release of PRO data to consumers.
- Congress should require HCFA and Medicare contracting HMOs to provide a range of quality of care information to Medicare beneficiaries.
- Congress should require HCFA to promulgate long-overdue HMO intermediate sanction regulations.

### **VII. THE HEALTH SECURITY ACT DOES NOT ADDRESS KEY ISSUES OF THE FINANCIAL RISK ASSUMED BY MANAGED CARE PLANS AND THEIR CONTRACTING MEDICAL GROUPS**

We know little about the relationship of financial risk in managed care plans (who is at risk, for how much, and for what services) and patient care outcomes. As the General Accounting Office has warned on several occasions, placing too much financial risk on either managed care plans or contracting provider groups is a recipe for disaster. Within the Medicare HMO risk program, most contracting provider groups are at risk for all Part B service and at partial risk for some Part A services. Based on CHCR's study of Medicare risk-contract HMOs (CHCR, 1993), I believe that this risk results in some provider groups denying expensive medical services.

CHCR's study was unable to obtain any specific information on the amount of financial risk under which contracting HMO physician groups operate. However, based on knowledge obtained through CHCR's client cases and the study's survey, it is apparent that a few provider groups and HMOs have sacrificed patient care for profit. For example, a home health executive told CHCR that, given the number of HMO enrollees in one HMO contracting medical group, she expected to see 450 home health visits each month; instead, the group ordered an average of only 60 visits each month.



In any managed competition system, government oversight is critical to ensure that plans and subcontracting medical groups do not deny needed care in order to increase their profit margin.

### **Recommendations**

- Plans should be required to publicize the financial risk arrangement employed (e.g., who is at risk, for what services, and for how much money);
- The financial risk of individual providers and provider groups should be limited;
- The government should set limits on the profits any managed care plan can earn. Profits above the limit should go into added enrollee benefits.
- Congress should strengthen Medicare HMO due process protections, including the establishment of an expedited review system (see below).

## **VIII. ADDITIONAL COMMENTS ON CONSUMER PROTECTIONS**

Although today's hearing is on quality of care, I would like to place in the record CHCR's concerns with the lack of adequate consumer due process and marketing protections in the Health Security Act. Due process is inextricably intertwined with ensuring quality of care.

### **Due Process Protections**

The Due process protections in the act are inadequate to protect managed care enrollees. For example, they would not address the problem encountered by Ms. S., a Medicare HMO enrollee.

Mrs. S is a 73-year-old Medicare beneficiary suffering from chronic pulmonary disease (a lung disorder). Mrs. S. lives in Los Angeles and, like one-third of the Medicare population in the County, belongs to a Medicare risk-contract HMO. In December 1993, while visiting relatives in San Diego, she was hospitalized as an emergency patient and placed on a ventilator to help her breathe. Her attending physician felt strongly that if she was discharged to a rehabilitation hospital for acute respiratory therapy, she could be weaned from the ventilator and return home. The attending physician also believed that if she was not weaned, she would die.

The HMO refused to approve the transfer, instead offering to discharge Mrs.

S. to a less costly nursing home, which could not wean her from the ventilator. Ms. S.'s family sought help from the Center for Health Care Rights. After two frustrating days of attempting to work with the HMO on Ms. S.'s behalf, the HMO acknowledged the need to wean Mrs. S. but still did not authorize rehabilitation care. It was only after the Center's Director of Litigation advised the HMO's officers that she would be appearing in court the following morning to obtain a temporary restraining order that the HMO approved Ms. S.'s the transfer to the rehabilitation hospital.

Although the Center was finally able to help Mrs. S. obtain appropriate care, without the Center's intervention, she might well have been transferred to a nursing home, where she would have remained while her appeal slowly made its way through the system.

## **Recommendations**

### **Notice of Appeal Rights**

Congress should clarify the circumstances for providing notice to patients when decisions to deny, reduce, or terminate a service or payment has occurred. Specifically, notice provisions of the Act should be strengthened to include the following:

- Notices should be triggered automatically when certain benefits, such as hospital, nursing home, in-patient rehabilitation, and home health care, have been denied, reduced or terminated;
- Notices should state the specific reasons for the decision and describe the appeals process available to the patient;
- All plans should be required to provide enrollees with periodic notices of their appeal rights and prominently place notices describing appeal rights in provider waiting rooms.

### **Need for Independent Expedited Review**

CHCR's study of Medicare HMOs and extensive experience with HMO enrollees leads us to conclude that, without an expedited review system, an appeals system is useless in cases of underservice. The appeals process takes months. Often managed care enrollees denied needed care do not have months to wait for service. Even short delays in the provision of services, such as home health care, rehabilitation services, MRIs, specialty care and surgeries can have harmful and irreversible effects. The Coalition strongly recommends the following additions to the appeals process:

- All managed care enrollees should have available to them an expedited appeals system for denials/delays in treatment that could seriously jeopardize their health or well being; and
- The expedited review should be heard by an *independent* monitoring organization, outside of the plan, that would render a decision within 24 hours. (PRO review of contested hospital discharges of Medicare patients is an example of how an expedited review system might be structured.)

### **Shortening of Appeal Time Period**

The Health Security Act gives plans 30 days to make a decision on an initial appeal and an additional 30 days to make a second decision on a request for reconsideration. The Health Security Act also requires that all claimants must first go through the initial and reconsideration stages prior to appealing to a state Complaint Review Office.

- The reconsideration stage of the appeal process should be eliminated, allowing enrollees to directly appeal to the Complaint Review Office following a plan denial of the initial appeal; or
- The time allowed plans to make initial and reconsideration decisions should be shortened to 15 days.

### **Point-of-Service Option**

As discussed above, CHCR believes that the ability of consumers to obtain services outside of a managed care plan is a basic due process protection. CHCR recommends that:

- The requirement that managed care plans offer a point-of-service option for enrollees be retained in the Health Security Act.

### **Plan Marketing Controls**

The Health Security Act requires alliances to approve all plan marketing materials. The history of both Medicare and Medicaid HMOs provides ample evidence that HMO marketing activities are open to serious abuse.

Report cards with outcomes and other quality of care measures are critical if consumers are to make informed decisions on which health plan to join. However, if alliances control of marketing are not adequate, plan marketing activities (including television, radio and print advertisements, celebrity spokespersons, and the actions of individual marketing agents) could undermine the report cards' effectiveness. At a minimum, marketing of managed care plans should be limited in the following ways:

- Limiting the percentage of plan revenues that can be spent on marketing;
- Requiring all plan marketing materials to contain specified report card information; and
- Prohibiting door-to-door and any in-home marketing.

## CONCLUSION

Many proponents of managed competition believe that stricter quality oversight of managed competition plans is unnecessary. CHCR's experience representing vulnerable populations leads us to draw the opposite conclusion. Consumer satisfaction with the quality of health care will be the foundation upon which the popularity of any government-sponsored health care reform rests. As the recent Los Angeles earthquake demonstrates, strong foundations are critical.

Congressman Waxman and Committee members, thank you for providing CHCR with the opportunity to present its concerns with the quality and consumer protections in the Health Security Act. We look forward to the time that this nation has a health care system for all.



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## INTRODUCTION AND BACKGROUND TO STUDY

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### BACKGROUND

Health Maintenance Organizations (HMOs) are a relatively new, but increasingly important, part of the Medicare program. Promoted by the federal government, Medicare HMOs have grown rapidly, especially in California where HMO enrollment accounts for approximately 15 percent of the Medicare population. Between 1989 and 1991, Medicare HMO enrollment grew in California at the rate of 20 percent per year to over .5 million enrollees.

There are basically two types of Medicare HMOs: cost-contract HMOs paid the actual costs of providing care; and risk-contract HMOs paid a capitated rate per Medicare enrollee in return for providing Medicare covered services. This study looks at the care provided by California's Medicare risk-contract HMOs.

The Medicare Advocacy Project, Inc. (MAP) is a non-profit organization that provides free education, counseling and legal assistance to Medicare beneficiaries in Los Angeles County. Through its Health Insurance Counseling and Advocacy Program (HICAP) staff and Volunteer Counselors,<sup>\*</sup> MAP assists over 6,000 Medicare beneficiaries annually. Approximately thirty percent of MAP's work load relates to HMO issues. This study is an outgrowth of MAP's concern that Medicare HMO enrollees receive high-quality care in both the fee-for-service (FFS) and HMO systems.

### Advantages and Disadvantages of HMO Enrollment

Joining an HMO offers a number of advantages for Medicare beneficiaries including a significant reduction in their out-of-pocket costs for supplemental health insurance and Medicare cost-sharing, elimination of paper work and added benefits not covered by Medicare.

HMOs also have a number of disadvantages for Medicare beneficiaries including a restricted choice of physicians and hospitals and a requirement that enrollees use only HMO providers except in emergencies or out-of-area urgent situations.

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<sup>\*</sup>HICAP is supported by a grant from the California Department of Aging with funding from the California Department of Insurance.

## **Government Oversight of HMOs**

Both the federal and state governments are responsible for ensuring that Medicare HMO enrollees receive high quality care. The federal Health Care Financing Administration (HCFA) has general oversight responsibility for monitoring the care provided Medicare HMO enrollees. HCFA Region IX is the contact for risk-contract HMOs in California.

California Medical Review, Inc. (CMRI), working under a HCFA contract, monitors the quality of care provided by California HMOs through reviews of hospital and outpatient charts.

The California Department of Corporations (DOC) is mandated by the state's Knox-Keene Health Care Service Plan Act of 1975 to license and oversee all California HMOs. DOC has oversight responsibility for the financial stability and quality of care provided by HMOs and health care services plans licensed in the state.

## **STUDY DESIGN**

### **Objectives**

This study looks at California Medicare risk-contract HMOs to learn more about how they operate and the regulatory system that governs them. The study has several objectives:

- to examine how Medicare risk-contract HMOs operate;
- to determine the types of data available to evaluate HMOs and how these data can be used;
- to assess HMO marketing programs, quality of care systems, and due process protections; and
- to determine the effectiveness of federal and state oversight of risk-contract HMOs

## **Methodology**

### **Study HMOs**

The study reviewed the 10 largest risk-contract HMOs serving California Medicare beneficiaries as of July 1991--Aetna's Partners Plan (Aetna/Partners), Aetna Northern California (Aetna N.CA), Bridgeway, CareAmerica, Family Health Plan (FHP), Inter Valley Kaiser Permanente Southern California Region (Kaiser SCR), Qual-Med Health Plan (recently known as PCA), Pacificare's Secure Horizons, and United Health Plan (UHP)

Table 1 contains information on these 10 HMOs, which account for 72 percent of all Medicare HMO enrollees in the state.

### **Data Sources**

This study was based on a number of data sources: information from federal and state agencies with HMO oversight responsibility; interviews with HCFA, CMRI, and DOC Staff; information provided by some of the study HMOs; surveys of consumer groups and health care provider organizations; and on-site monitoring of selected HMO presentations.

Obtaining information from HCFA and DOC was very time-consuming. Following almost a year's delay and a court mandate, HCFA responded to the study's Freedom of Information Act (FOIA) requests, sending data on HMO enrollments, disenrollments, marketing materials, monitoring reports, complaints, contracts and Medicare appeals. After significant effort, MAP also obtained monitoring and HMO financial reports from DOC.

In addition, MAP analyzed data from CMRI on HMO and FFS hospital discharge rates by Diagnosis Related Groups (DRGs) for 1989, 1990 and the first half of 1991.

MAP contacted the 10 study HMOs, asking that they fill out a detailed questionnaire about their organizations. Six of the ten study HMOs responded to the questionnaire--Aetna N.CA, Bridgeway, CareAmerica, Inter Valley, Kaiser SCR, and Secure Horizons. Aetna N.CA, Bridgeway, CareAmerica and Inter Valley provided the most information. Aetna/Partners, Qual-Med, FHP and UHP did not respond to MAP's request for information.

To obtain additional information about HMO practices, MAP surveyed a number of other consumer organizations as well as health care providers--home health agencies (HHAs), hospital discharge planners and rehabilitation providers. Because of limited staff resources, MAP was unable to follow-up on all of the surveys mailed out. Thus, the sample size of respondents is small (22 hospital social workers, 14 home health agencies, and six rehabilitation providers) and survey results may reflect a biased self-selection by some providers.

### **DISCUSSION**

Most of the information included in this study has never before been released to the public. Some of the data upon which MAP bases its analysis is imperfect. It is presented because MAP believes that its analysis and publication is an important first step in meeting the need of beneficiaries for additional information on HMOs. MAP hopes that its analysis will encourage government agencies to improve their HMO data collection systems and make public their own HMO comparisons.

TABLE 1  
CALIFORNIA RISK-CONTRACT HMOs

HMO	Date of Risk-Contract	Medicare Enrollment as of 7/92	Medicare Enrollment as % of Total Enrollment	Type of HMO (Model)	Profit/Non-Profit	Geographic Area Served (by County)
Aetna/Partners	8/86	35,221	33.1*	IPA	Profit	Parts of Riverside, San Bernardino & L.A.
Aetna M.C.A.	2/86	14,134	12.6**	IPA	Profit	San Mateo, San Francisco & Marin
Bridgeway	10/85	9,797	14.5** 15.1***	Staff & Network	Profit	San Francisco, parts of San Mateo & Marin
CareAmerica	11/90	7,299	0.8** 3.5***	IPA	Profit	Parts of L.A. & Orange
FNP	4/85	167,909	32.1**	IPA & Staff	Profit	Orange, parts of L.A., Riverside, San Bernardino, San Diego & Ventura
Inter Valley	6/86	12,582	25.4** 30.2***	IPA (2% Group)	Non-Profit	Parts of L.A., Riverside, San Bernardino & Orange
Kaiser SCR	9/87	104,323	6.6** 6.4***	Group	Non-Profit	Parts of L.A., Orange, Riverside, San Diego, San Bernardino & Ventura
Qual-Med	7/85	6,499	21.9**	Group	Non-Profit	Sacramento, Butte, Colusa, Glenn, Sutter, Yuba, parts of El Dorado, Placer, Yolo, Plumas, Sierra & Solano
Secure Horizons	9/85	157,585	23.3**	IPA & Network	Profit	Santa Barbara, Kern, parts of L.A., Orange, Riverside, San Bern., San Diego
United Health Plan	4/85	13,139	18.9*	Staff & Group	Non-Profit	Parts of L.A. & Orange

\* 1990

\*\* 1991

\*\*\* First Quarter 1992

Sources: Health Care Financing Administration, On-Site Review Reports; Monthly Report, Medicare Prepaid Health Plans, July 1992; Responses to MAP Inquiries November 7 & 21, 1991 and August 3, & 31 1992; Responses to MAP questionnaire from Aetna M.C.A., Bridgeway, CareAmerica, Inter Valley, Kaiser SCR, and Secure Horizons.



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## MARKETING

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### BACKGROUND

The range of marketing activities undertaken by HMOs varies considerably depending on the HMOs' size, organizational model, dependence on Medicare enrollees, and location in a competitive market.

Common HMO marketing practices include: television and radio advertisements; newspaper advertisements; mass mailings to seniors; telemarketing; community presentations and visits to Medicare beneficiaries' homes.

### MARKETING/ENROLLMENT PROBLEMS

MAP has documented and reported many cases in which HMO marketing agents have enrolled mentally confused or otherwise vulnerable seniors; pressured Medicare beneficiaries to enroll; lied about the HMO benefits and enrollment procedures; and forged beneficiary signatures.

The following are examples of the types of marketing problems presented in the study:

#### The Case of Mrs. J.

The following is from a 1991 letter sent to a Southern California HMO by the daughter of a recently enrolled beneficiary:

"I want you to be aware of a serious concern I have regarding your organization. My mother, an 82-year-old widow who has been diagnosed by UCI Medical Center's Alzheimer's Clinic as having dementia, was visited at home by a sales person from your company . . . . Anyone who talked with my mother by phone or in person would clearly know that she is not able to comprehend the provision of any such medical policy. Yet seeing this, your sales person had her sign something which she did obviously not understand."

### The Case of Mr. B.

Although illiterate, Mr. B was asked to initial and sign an HMO enrollment form under the following circumstances:

"I was sitting on the corner of Jefferson and Griffith Streets socializing with a bunch of friends. A young man came to talk to us, telling us that his health program was good for elderly people, and promised I could get my new glasses the next day, so I signed up."

### The Case of Ollie T.

Ollie T., a long-time Kaiser SCR member, was visited by a marketing representative from another HMO. Mr. T. informed the agent that he wanted to remain in Kaiser SCR. The marketing agent asked Mr. T. to sign a paper to document that she had been to his home. Stating that she needed to get her business card and other papers from her car, the HMO representative left and did not return. Several months later, Kaiser SCR informed Mr. T. that he owed back premiums because he was no longer in their Medicare plan. This was the first notice that Mr. T. had that he was enrolled in another HMO.

Medicare beneficiaries who experience HMO marketing excesses frequently suffer emotional and financial harm. Unaware that they are enrolled in an HMO or confused about how HMO enrollment affects access to Medicare benefits, they may continue to use non-HMO physicians and hospitals. When HMO enrollees use out-of-plan providers for non-emergency care, neither Medicare nor the HMO will pay.

At least part of the blame for marketing problems lies with the financial incentives that HMO marketing staff to enroll as many beneficiaries as possible. Because their income is usually partially dependent on commissions, the more beneficiaries they sign up, the more they earn.

## **HMO MARKETING MATERIALS AND PRESENTATIONS**

Both HCFA and DOC have detailed legal standards for HMO marketing activities and materials, making illegal: engaging in discriminatory practices that discourage enrollment on the basis of health status; activities that could mislead or confuse Medicare beneficiaries or misrepresent the organization; offers of gifts or payment as inducement to enroll; and door-to-door solicitation of Medicare beneficiaries.

### **Analysis of Medicare HMO Marketing Materials**

In its analysis of HMO marketing materials, MAP determined that HCFA generally does a careful job of scrutinizing these materials to ensure that they meet federal requirements.

MAP, however, found four areas of concern:

- Lack of adequate HMO identification;
- Inappropriate use of marketing materials to contact beneficiaries;
- Implication that Medicare risk-contract HMOs restrict enrollment to seniors and exclude Medicare disabled beneficiaries; and
- Lack of translated marketing materials.

Because HMO materials are reviewed by HCFA, DOC often defers to HCFA's review process.

### **Analysis of HMOs' Marketing Presentations**

Medicare beneficiaries often learn about HMOs by attending an HMO marketing presentation. To judge the accuracy of the marketing presentations, MAP staff, accompanied by a Medicare beneficiary, attended two marketing presentations each by four Southern California HMOs.

Generally, MAP found that the marketing presenters provided accurate information on enrollment, lock-in and HMO benefits, but were less accurate in other less critical areas. Many of the HMO representatives failed to adequately explain the disenrollment process and coverage of emergency and urgent care/out-of-plan area travel. Further, many of the HMOs misrepresented the Medicare FFS program and the advantages of their own plans. MAP's overall assessment, however, is that Medicare beneficiaries attending the presentations left with an accurate picture of how HMOs worked and the implications of HMO enrollment.

### **DISENROLLMENT AND COMPLAINT DATA**

Beneficiaries who have been improperly enrolled are likely to disenroll from the HMO once they learn of the enrollment. Thus, one indication of marketing problems is a high disenrollment rate.

The study presents a number of analyses of disenrollment information obtained from HCFA. Enrollments are classified as voluntary or involuntary. Involuntary disenrollments are initiated by the HMO for reasons such as death, a move out of the area, or failure to pay plan premiums.

Table 2 provides disenrollment data for 1991 that assumes no new enrollment during the year. It indicates the percentage of an HMO's January 1991 enrolled population that would have disenrolled during the year if there had been no new enrollees.

TABLE 2

**DISENROLLMENTS BY HMO AS A PERCENT OF JANUARY 1, 1991  
BASE ENROLLMENT**

HMO*	1/91 Base Enrollment	Tot. (% of Disen.** base)	Vol. (% of Disen.** base)	% of Disen. that are Vol.
Aetna/ Partners	25,577	3561 (13.9%)	2737 (10.7%)	77%
Aetna N.CA	12,789	775 ( 6.1%)	409 ( 3.2%)	53%
Bridgeway	7,914	414 ( 5.2%)	267 ( 3.4%)	65%
FHP	134,920	27,865 (20.7%)	23,487 (17.4%)	84%
Inter Valley	8,877	1,068 (12.0%)	768 ( 8.7%)	72%
Kaiser SCR	86,680	6,941 ( 8.0%)	4,820 ( 5.6%)	69%
Qual-Med	3,298	461 (14.0%)	396 (12.0%)	86%
Secure Horizons	106,942	12,193 (11.4%)	9,202 ( 8.6%)	76%
UHP	10,219	2,106 (20.6%)	1,793 (17.5%)	85%

\* Because CareAmerica's base enrollment in January 1991 was less than 1000, its plan was omitted from this analysis.

\*\* Disenrollment data for nine months only. Data for January, August and September 1991 not available.

Source: HCFA, *Monthly Disenrollment Patterns, Region IX*

Among the three largest Medicare HMOs in California - FHP, Secure Horizons and Kaiser SCR - FHP has the highest disenrollment rates. UHP had the worst record among the smaller HMOs. Looking at percentage of voluntary disenrollments, the large voluntary disenrollments from UHP and Qual-Med among the smaller plans, and FHP among the large plans, indicate that these HMOs may be inappropriately enrolling Medicare beneficiaries.

One way to assess the possible reasons for voluntary disenrollment is to analyze the period in which disenrollment takes place. A high rate of disenrollment within the first three months of enrollment is likely to reflect problems with an HMO's marketing division. Table 3 provides additional information that a problem may exist in the marketing division of FHP, UHP and Qual-Med.



TABLE 3

## 1991 Voluntary Disenrollment by HMO by Month\*

HMO	Voluntary Disenrollment	Voluntary Disenrollment by Months-In-Plan** (% of total)				
		0 Mo.	1 - 3 Mos.	4 - 6 Mos.	7 - 12 Mos.	13+ Mos.
Aetna/Partners	2737	288(10.5%)	367(13.4%)	242( 8.8%)	336(12.3%)	1494 (54.6%)
Aetna N.C.A.	409	13( 3.2%)	28( 6.9%)	18( 4.4%)	43(10.5%)	307 (75.1%)
Bridgeway	267	10( 3.7%)	15( 5.6%)	16( 6.0%)	16( 6.0%)	210 (78.7%)
FHP	23487	4658(19.8%)	4884(20.9%)	2312(9.8%)	3059(13.1%)	8534 (36.4%)
Inter Valley	768	37( 4.8%)	108(14.8%)	80(10.4%)	122(15.8%)	421 (54.8%)
Kaiser SCR	4820	164( 3.5%)	456( 9.5%)	283( 5.9%)	485(10.1%)	3431 (71.2%)
Qual-Med	396	68(17.2%)	83(21.0%)	49(12.4%)	75(18.9%)	110 (27.8%)
Secure Horizons	9202	769( 8.3%)	1139(12.4%)	801( 8.7%)	1382(15.0%)	511 (55.5%)
UHP	1793	229(12.8%)	356(19.9%)	157( 8.8%)	207(11.5%)	844 (47.1%)
CA Totals		15.1%	17.2%	9.5%	13.7%	44.4%
National Totals		10.7%	14.7%	9.1%	13.2%	52.4%

\* Because CareAmerica only began enrolling beneficiaries in December of 1990, the plan's disenrollment data were omitted from this Table.

\*\* For nine months: data for January, August and September 1991 not available.

Source: HCFA, *Monthly Disenrollment Patterns Region IX - Risk HMOs*.

At 40.7 percent, FHP has the greatest percentage among all HMOs of voluntary disenrollment within three months of enrollment. Qual-Med and UHP have the worst disenrollment records among the smaller plans.

Another potential source of information on enrollment and disenrollment problems is HCFA's Beneficiary Inquiry Tracking System (BITS), which analyses Medicare beneficiary "inquiry/complaint" data (Table 4, page 15). Because HCFA does not notify beneficiaries that they should contact the agency with their HMO complaints, and because the data does not differentiate between valid and invalid complaints, the BITS data are flawed. However, these data can help government monitoring agencies and consumers to ascertain whether a particular area of HMO operations needs further investigation.

Among the large HMOs, FHP once again has the worst record per enrolled population with 1059 inquiries/complaints on enrollment/disenrollment issues during a three year period. Beneficiary inquiries/complaints also indicates that UHP may have had a marketing problem. From 1989 to 1991, the plan had the greatest number of enrollment/disenrollment inquiries/complaints per 1000 enrollees. UHP had six times more complaints in this area than did Inter Valley, a plan of comparable size.

The disenrollment and complaint data presented here are consistent and paint one picture: during the years 1989 - 1991, FHP and UHP had serious marketing problems. Moreover, some of the data also raise concerns about Qual-Med's marketing. By contrast, it appears that most of the Medicare HMOs in California have experienced few marketing problems.

### THE CASE OF FHP

For a number of years, advocacy groups in Southern California noted a problem with FHP's aggressive marketing tactics. Yet, despite complaints from these groups and beneficiaries, as well as its own disenrollment data, it took HCFA over three years to finally address the problem. At least as early as the summer of 1988, HCFA found significant FHP violations of its marketing regulations at its bi-annual monitoring visit. However, despite numerous follow-up visits and bi-monthly meetings with FHP staff, it was not until August of 1991 that HCFA required FHP to change its marketing practices.

As of the summer of 1992, FHP does appear to have addressed its marketing problems. Nevertheless, MAP is concerned about the quality of HCFA's response to a well documented problem. Despite clear and constant indications of a pattern of systemic marketing abuse, FHP was able to violate HCFA marketing and enrollment regulations with near impunity for a number of years.

### DISCUSSION

The data presented in this chapter are consistent: during the years 1989-1991, FHP and UHP had marketing problems. Moreover, some of the data also raise concerns about Qual-Med's marketing.

By contrast, MAP's analysis of marketing materials and presentations and the data presented here indicate that most of the Medicare risk-contract HMOs in California are accurately informing Medicare enrollees of what it means to join an HMO.

Since the FHP marketing abuse case, HCFA is paying closer attention to disenrollment statistics. MAP views this as a positive step in preventing future marketing problems. Without better response by government agencies, the case of FHP might easily be repeated as new HMOs seek short-term profit by enrolling unsuspecting Medicare beneficiaries.

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## QUALITY OF CARE

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### BACKGROUND

Risk-contract HMOs operate very differently than fee-for-service (FFS) providers. The structures of these two health delivery systems create different financial incentives. In the Medicare FFS system, the incentive is to provide a high number of services, some of which may be unnecessary and harmful.

The opposite financial incentives, to provide less care, operate in the HMO system. A system that puts providers at financial risk for expensive medical treatment inherently contains incentives to deny needed care. The degree of financial risk--and who bears it--varies dramatically by HMO. Most California HMOs place the individual provider or subcontracting medical group at substantial financial risk.

Medicare HMO enrollees are protected to some extent against underservice or denial of needed care by federal law, which permits them to disenroll from an HMO at any time. However, disenrollment is not instantaneous and many HMO enrollees may feel that they cannot afford to disenroll and pay the out-of-pocket costs required in the Medicare FFS system.

### FEDERAL AND STATE OVERSIGHT RESPONSIBILITY

Both federal and state governments have responsibility for ensuring that Medicare HMOs provide high quality care. The HCFA Region IX office is responsible for bi-annual on-site monitoring reviews and addressing beneficiary complaints/questions. Working under a HCFA contract, CMRI monitors quality of hospital care provided to all California Medicare beneficiaries (including those in HMOs) through on-going patient chart reviews. To monitor quality, California's DOC conducts on-site medical surveys at least once every five years and investigates enrollees' complaints.

### PROBLEMS

MAP client cases and surveys done for this study indicate that the HMO referral process can result in delays or denials of needed care. The process by which an HMO patient is referred for specialty physician care and costly specialty services, such as MRIs,

nursing home, home health and inpatient rehabilitation services, varies by HMO and by subcontracting medical group. Often, the decision does not rest with the referring physician. Instead the HMO's subcontracting medical group's utilization review department makes the referral decision.

### **Access to Primary Care Physicians/Specialty Referrals**

Access to primary care HMO physicians is not a major problem. HMOs give new enrollees a list of primary care physicians from which they can choose. The only significant access barriers to HMO primary care physicians occur when contracting physician offices are closed to new patients; when an HMO's listing of primary care physicians becomes outdated; or when patients are forced to make appointments with different doctors because their primary care physician is frequently not available.

A far more serious access problem occurs when an HMO does not have enough contracting specialty physicians or when, because of financial considerations, subcontracting medical groups delay or deny referrals to these specialists.

The study includes a number of stories which illustrate the harmful delays some HMO enrollees face in obtaining specialty referrals:

- One HMO enrollee, suffering from an acute headache, numbness and blurred vision, had to wait almost a month before obtaining a referral to a neurologist. Going out-of-plan to an ophthalmologist for a free eye exam, she was told that there was evidence of a possible aneurism, blood clot or brain tumor. When she finally saw the HMO neurologist, he looked at her file and said that "you should have seen me three weeks ago."
- A rehabilitation inpatient coordinator wrote to MAP about her father who had "cardiac problems: despite persistent angina, no follow-up tests were ordered. When we demanded service, the HMO doctor responded, 'Your father isn't my only patient, you know.' My father subsequently saw an out-of-plan physician, who scheduled a quadruple bypass within three days."
- The niece of an HMO enrollee contacted MAP about the difficulties her uncle had in obtaining cataract surgery through an HMO. Although the primary care physician stated that cataract surgery was badly needed (his patient could no longer read or drive a car), the HMO's medical group, despite repeated promises, would not schedule the surgery. After more than a year's delay, the HMO enrollee obtained the surgery out-of-plan and is appealing the HMO's denial of payment.



## Access to Post-Hospital Care

MAP's study uncovered few access problems relating to hospital admissions. However, access to post-hospital care is another story. Our survey of home health agencies, rehabilitation providers, and hospital discharge planners as well as a number of MAP client stories raise questions about the process by which HMO enrollees obtain post-hospital care.

Several of the 22 hospital social workers surveyed had positive opinions of the HMO referral process. However, when asked if there were particular types of services generally denied HMO patients, 15 stated that they had difficulty obtaining authorization for a number of post-hospital follow-up services including home health services, durable medical equipment, acute care rehabilitation and skilled nursing facility care, ongoing follow-up care, and physical therapy.

Many hospital social workers and other providers surveyed noted that when authorization is granted, it is often only after much argument and discussion. For example, one survey respondent complained that the HMO will "usually authorize" care but that "great energy [must be] used by the discharge planners. A lot of time is wasted in red tape and authorization. I spend two to three times the amount of time trying to get services compared to Medicare [FFS] covered patients."

Survey respondents provided the following examples of the difficulty faced in obtaining post-hospital referral services:

"Ms. A entered our hospital for a hip replacement due to degenerative joint disease. She came with her own walker which our therapists deemed to be too short for her. Also, two of the legs of the walker were bent and so uneven that they were not even on the floor. I asked her HMO for a new walker and an over the toilet commode . . . The HMO authorized the commode but would not authorize a new walker even though the patient stated that the walker she came in with had been acquired at a swap meet!"

"[The HMO] does not authorize home health aides. They make patients pay for it out of pocket. In a recent meeting with the UR [utilization review] Manager at the [medical group], she told me to 'quit having your nurses bug me about home health aides.' She said she knows it's covered by Medicare but they [the HMO] consider it custodial and will not cover it."

"The patient had suffered a severe head injury as the result of a car accident . . . It took the HHA three weeks to get authorization of needed medical equipment. There was a one month delay in authorizing inpatient rehabilitation . . . With the assistance of the HHA and the HMO physician, the patient was finally admitted [for rehabilitation] but only for seven days. When the client returned home, he became bedridden again."

Survey respondents also reported that, rather than denying services outright, HMOs approve "less care" than needed. For example, seven of 10 surveyed HHAs stated that they had far greater difficulty obtaining home health authorization for HMO patients than for FFS Medicare patients. For example, one respondent noted that:

"An [HMO] stroke victim will get 1 to 2 nursing visits. In contrast, a Medicare FFS patient will get 3 to 4 nursing visits, 4 to 5 home health aide visits, and rehabilitation each week with the number of visits decreasing as the patient improves."

Some of the survey respondents expressed particular concern about a specific HMO or medical group, noting that the other HMOs or groups with which they dealt referred cases when appropriate. For example, one home health consultant, who had worked with a number of HMOs and subcontracting medical groups as an executive with a large home health agency, told MAP how alarmed she was by one medical group, which contracts with several different HMOs. For the group's number of HMO enrollees, the consultant expected to see an average of 450 home health visits a month, instead of the 60 authorized by the group.

### **INQUIRY/COMPLAINT DATA**

To assess whether access to quality services is a problem in any of California's risk contract HMOs, MAP requested a wide range of data from the HMOs themselves and from a number of government agencies. Unfortunately, data are not readily available.

HCFA, CMRI and DOC use complaints to alert them to possible quality of care problems. These government agencies receive relatively few complaints; however, new HMO enrollees receive no information instructing them to contact HCFA, DOC or CMRI if they have a quality of care problem. Only HCFA was able to provide any accounting of the number and types of complaints it receives through its Beneficiary Inquiry Tracking System (BITS). Table 4 presents BITS data from the years 1989-91.

Although BITS data should be viewed with caution, it can be useful in assessing, at least at a gross level, potential HMO problem areas. Comparing the three largest Medicare HMOs for the years 1989-1991, FHP has the greatest number of inquiries/complaints per enrolled population (1.09) compared to Secure Horizons (.47) and Kaiser SCR (.80). Among the smaller plans, UHP has the worst three year inquiries/complaints record at 2.10 per thousand enrollees.

### **UTILIZATION DATA**

Comparing utilization rates between Medicare HMO enrollees and FFS Medicare beneficiaries might provide some information on whether treatment patterns in the two systems differ. Unfortunately, state and federal HMO monitoring agencies collect very little data on utilization rates and have failed to analyze the data that is collected.

TABLE 4

**BENEFICIARY INQUIRY TRACKING SYSTEM  
HMO INQUIRIES/COMPLAINTS, 1989 -1991**

HMO	Quality of Care  Tot. (# per # 1000 enroll.)*	Enroll/ Disenroll  Tot. (# per # 1000 enroll.)*	Payment/ Claims  Tot. (# per # 1000 enroll.)*	Miscellan- neous  Tot. (# per # 1000 enroll.)*	Total (1989-91)  Tot. (# per # 1000 enroll.)*
Aetna/ Partners	12 (0.17)	145 (1.99)	7 (0.10)	201 (2.52)	365(1.19)
Aetna N.CA	2 (0.05)	54 (1.48)	3 (0.08)	71 (1.91)	130 ( .88)
Bridgeway	0 (0.00)	39 (1.79)	2 (0.09)	44 (1.93)	85 ( .95)
CareAmerica**	0 (0.00)	2 (1.14)	0 0	11 (6.91)	13 (2.01)
FHP	62 (0.16)	1059 (2.79)	56 (0.15)	476 (1.29)	1653 (1.09)
Inter Valley	3 (0.11)	16 (0.67)	2 (0.09)	61 (2.23)	82 ( .73)
Kaiser SCR S. CA	15 (0.06)	299 (1.22)	12 (0.02)	481 (1.88)	807 ( .80)
Qual-Med***	3 (0.38)	6 (0.68)	0 (0.00)	31 (3.35)	40 (1.10)
Secure Horizons	44 (0.15)	155 (0.57)	19 (0.07)	324 (1.05)	542 ( .46)
UHP	5 (0.16)	97 (3.06)	10 (0.31)	186 (5.90)	298 (2.10)

\* Obtained by averaging the number of monthly enrollees per year

\*\* Data for 1991 only. Because of small enrollment, inquiries/complaints per 1000 enrollees is not an accurate indication of any problem.

\*\*\* Because of small enrollment, inquiries/complaints per 1000 enrollees is not an accurate indication of any problem.

Source: HCFA, *Beneficiary Inquiry Tracking Subsystem: Workload Summary*

### Hospitalization Rates by Diagnosis: HMOs vs. FFS

MAP analyzed CMRI age and sex adjusted hospital utilization data for California Medicare HMO and FFS beneficiaries. The data covered 1989, 1990, and the first half of 1991.

Table 5 shows 1989 - 1991 hospitalization rates as discharges and hospital days per 1000 Medicare beneficiaries for FFS and HMO patients and hospital days. The table shows that Medicare FFS beneficiaries were 1.5 times more likely to obtain hospital care in 1989 than were HMO enrollees, 1.7 times more likely to obtain this care in 1990 and more than 2 times more likely to be hospitalized in 1991.

These differences were present for all the Diagnosis Related Groups (DRGs). For example, Medicare beneficiaries in the FFS sector are almost three times as likely to undergo coronary bypass surgery than are Medicare HMO enrollees.

**TABLE 5**

#### HOSPITALIZATION RATES AND BED DAYS PER 1000 BENEFICIARIES FFS VS. HMO: 1989-1991

YEAR	FFS			HMO		
	Discharge Per 1000 Enrollees	ALOS*	DAYS Per 1000 Enrollees	Discharge Per 1000 Enrollees**	ALOS*	Days Per 1000 Enrollees**
1989	229.88	7.54	1742	158.31	6.03	967
1990	222.63	7.43	1660	132.85	5.72	764
1991***	221.21	7.49	1659	109.69	5.66	625

\* Average length of stay (in days)

\*\* Adjusted for age and sex to 1990 Medicare population

\*\*\* First half, annualized

Source: CMRI Medicare Advocacy Project Data Release: Age and Sex Adjusted Rates, May 27, 1992.

Several possible explanations exist for the differences MAP found in HMO and FFS hospital utilization:

- HMO enrollees are healthier than FFS patients;



- HMO patients receive better preventive care;
- Hospital services are overutilized in FFS and/or underutilized in Medicare HMOs;
- HMOs do not use hospitals for terminally ill patients; and/or
- The CMRI data are based on inaccurate reporting of HMO hospital data.\*\*

### **Variations in the Hospital Utilization Rate for Certain Procedures in the Three Largest Medicare HMOs**

Table 6 analyses the frequency of several commonly performed major procedures at the three largest Medicare risk-contract HMOs in California. The total number of beneficiaries in these three HMOs represented over 80 percent of all Medicare risk-contract HMO enrollees in California. Unlike the previous analysis comparing hospital utilization by HMOs and FFS, the data presented in Table 6 are not age and sex adjusted.

Even without adjustment for age and sex, MAP expected that the hospitalization rates for common DRGs would be fairly consistent among HMOs. This was not the case. MAP found significant variations among the HMOs. For instance, HMO C had a rate of cholecystectomies and major joint and limb procedures almost twice the average rate of the other HMOs. The most troubling finding was the low number of coronary bypass procedures performed by HMO A. An enrollee in HMO C was almost six times more likely to undergo bypass surgery than an HMO A enrollee.

MAP attempted to explain this variation by comparing the number of coronary bypass procedures to the admission rate for acute myocardial infarction. MAP felt this latter number would provide a rough estimate of the frequency of coronary artery disease in these HMOs. If HMO A had far fewer heart attack admissions than enrollees in the other HMOs, then arguably, the low number of coronary bypass procedures might be the result of a healthier and/or younger population. As Table 7 shows, HMO A performed many fewer coronary bypasses than the other HMOs based on the number of admissions for acute myocardial infarction.

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\*\*HCFA's response to MAP's draft study indicated HCFA was concerned that, because of reporting problems, the CMRI data might not be capturing all HMO hospital claims. CMRI, however, was more confident that its data reflected all Medicare hospitalizations, including those of HMO patients. MAP's analysis of the data, presented in the full report, indicates that HMO hospitalized patients may be healthier than FFS hospitalized patients, which would explain some of the difference in admission rates.

TABLE 6

**1990 HOSPITAL UTILIZATION PER 1000 ENROLLEES FOR SELECTED  
PROCEDURES BY THREE CALIFORNIA HMOs**

PROCEDURE (DRG NO.)	HMO			
	A	B	C	ALL**
MAJOR CHEST PROCEDURE (75)	0.36*	0.59	1.18	0.60
CORONARY BYPASS (106,107)***	0.34	1.13	1.94	1.08
MAJOR CV PROCEDURES (110,111)	1.3	0.94	1.53	1.17
PACEMAKER INSERTION (116)	1.0	0.71	1.52	0.97
MAJOR BOWEL PROCEDURES (148,149)	2.40	1.98	3.03	2.36
STOMACH, ESOPHAGUS, DUODENAL PROCEDURES (154,155)	0.67	0.57	0.77	0.64
CHOLECYSTECTOMY (195,196,197,198)	1.25	1.24	3.11	1.62
MAJOR JOINT & LIMB PROCEDURES (209)	2.98	3.76	6.07	3.97
HIP & FEMUR PROCEDURES (210,211)	1.95	1.90	2.34	2.03
MASTECTOMY (257,258)	1.11	1.29	1.64	1.22
PROSTATECTOMY (306,307)	0.37	0.42	0.31	0.37
TRANSURETHRAL PROCEDURES (310,311)	0.61	0.84	1.59	0.94
TRANSURETHRAL PROSTATECTOMY (336,337)	3.89	4.61	4.54	4.11
TOTAL NUMBER OF PROCEDURES	18.23	19.98	29.57	21.8
MEAN NUMBER OF PROCEDURES	1.4	1.54	2.27	1.68

\* All numbers are expressed per 1000 beneficiaries.

\*\* Average of all Medicare patients in California at-risk HMOs.

\*\*\* MAP combined DRGs for procedures which had been separated because of the presence of other illnesses (co-morbidities) or additional procedures (cardiac catheterization for coronary bypass surgery and common bile duct exploration for cholecystectomy)

Source: CMRI, DRG Summary for 1/1/89 thru 6/30/91: Individual HMOs vs. Aggregate HMO Totals.

TABLE 7

1990 UTILIZATION RATIO OF CORONARY BYPASS SURGERY RATES PER 1000 TO MYOCARDIAL INFARCTION RATE PER 1000 BY THREE CALIFORNIA HMOs

HMO	CORONARY BY-PASS RATE	MYOCARDIAL INFARCTION RATE	RATIO OF BY-PASS/INFARCT
A	0.34	5.43	0.06
B	1.13	3.74	0.30
C	1.94	8.25	0.24
COMBINED	1.08	5.19	0.21

Source: CMRI, DRG Summary for 1/1/89 thru 6/30/91: Individual HMOs vs. Aggregate HMO Totals.

MAP also examined whether the large difference in the rate of heart bypass operations might be explained by a greater use of angioplasty in HMO A. Angioplasty is a surgical procedure which is sometimes used instead of bypass operations. However, a comparison of the angioplasty hospitalization rates among the three HMOs showed no significant difference.

#### MONITORING OF RISK-CONTRACT HMOs

##### HCFA HMO On-Site Monitoring Reviews

HCFA monitors risk-contract HMOs bi-annually. A review of on-site surveys and accompanying correspondence for the 10 HMOs in MAP's study shows that, in general, HCFA does a thorough job in its bi-annual monitoring visits of documenting HMO quality of care and other deficiencies. Despite this overall positive assessment, however, MAP found a number of deficiencies in the monitoring process that should be addressed.

- HCFA does not adequately examine the risk arrangements in Medicare HMOs;\*\*\*
- A problem is found, but no recommendations for corrective action made;
- There is inadequate follow-up for problem areas;

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\*\*\*HCFA is currently testing a new on-site monitoring instrument which looks more closely at HMO risk-arrangements. The new survey requirements will provide significant added protections for Medicare HMO enrollees.

- The HCFA review process appears unable to address continuing problems;
- HCFA relies too heavily on HMO paper compliance;
- HCFA does not include in its monitoring activities surveys of HMO referral providers;
- HCFA's review of an HMO's quality assurance plan (QAP) does not adequately assess the effectiveness of the plan;
- HCFA does not incorporate beneficiary complaints into its monitoring survey; and
- HCFA provides no information to HMO enrollees or potential enrollees about significant problems found during on-site surveys.

Currently, HCFA's only leverage to compel HMO compliance with federal standards is either to halt an HMO's expansion into new areas or to terminate the HMO's risk contract. Contract termination is a very weak reed on which to rely. HCFA is justifiably reluctant to impose this sanction because of the disruption that termination would cause current HMO enrollees. The 1987 Omnibus Budget Reconciliation Act gave HCFA authority to impose intermediate sanctions on HMOs if they do not meet federal requirements. To date, four-and-one-half years later, HCFA has failed to promulgate regulations to give teeth to the law.

#### **DOC ON-SITE MONITORING REVIEWS**

DOC is responsible for monitoring all HMOs licensed in California. On-site surveys are performed once every five years, more often if DOC deems necessary. In many ways, DOC's monitoring visits are quite comprehensive. As with HCFA's monitoring efforts, however, MAP has a number of concerns.

- The frequency of DOC monitoring surveys is inadequate;
- The DOC survey process, which takes a minimum of 11 months, is too lengthy;
- Underservice and HMO risk arrangements are not closely scrutinized;
- DOC does not contact enrollees or other groups for input during its monitoring visits; and
- The initial survey reports, HMO responses and interim surveys are kept confidential.



## CMRI MEDICARE RECORDS REVIEW

CMRI conducts an ongoing assessment of the quality of care provided by Medicare HMOs by reviewing hospital and ambulatory medical records. Problems found in its review of claims are categorized by "severity level": Level 1 refers to "quality problems without the potential for significant adverse effect on the patient"; Level 2 refers to "quality problems with a potential for significant adverse effect on the patient"; and Level 3 refers to "quality problems with a significant adverse effect on the patient."

CMRI is required to "intensify" its review if a particular HMO reaches a threshold of confirmed problems and/or has a single Level 3 problem. In its review of over 14,000 HMO hospital claims from April 1, 1989 to September 30, 1990, CMRI found only 122 problem claims. Of these, however, 80 (66.6%) were at Level 2 or 3. Of reviewed claims, CMRI found almost three times more confirmed problems in HMOs (.83 percent) than in the FFS system (.29 percent).

Among all HMOs, UHP had the highest percentage of confirmed problems at 3.2 percent of claims reviewed. Among the three largest HMOs, FHP was found to have the largest percentage of confirmed problems and the most level 2 and 3 problems.

## DISCUSSION

The on-going monitoring of Medicare HMOs by government agencies provides a measure of protection for Medicare HMO enrollees. Compared to providers in the FFS system, HMOs receive a great deal of scrutiny. This scrutiny is, however, necessary. A closed system of health care, in which enrollees are "locked-in" to a particular plan, and the financial incentives for underservice in these plans are good cause for comprehensive oversight.

Readers should view the anecdotal cases described in this study with caution. HMOs do not have a monopoly on quality of care problems. Indeed there are likely as many, if not more, quality of care problems in FFS sector. However, HMO enrollee complaints, MAP's experience and the results of the study's surveys described above, raise the question of whether HMO financial incentives lead to systematic underservice, especially in the areas of specialty referrals, and home health, skilled nursing facility and rehabilitation services.

Unfortunately, federal and state agencies responsible for HMO oversight do not collect adequate data to assess the utilization patterns of Medicare HMOs. The HMO utilization data presented here is very limited and raise more questions than they answer. Further analysis is needed to assess the differences in utilization rates between HMOs and FFS, as well as among the different HMOs.

MAP's primary concern with the current oversight activities of HCFA, DOC and CMRI is the lack of attention to the potential for underservice in HMOs and the failure to provide information to Medicare beneficiaries to help them assess HMO quality of care.

HCFA has encouraged expanded enrollment in HMOs as a way to reduce Medicare costs. However, if HMOs are enrolling healthier patients, than any cost savings may be illusory.

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## **DUE PROCESS RIGHTS**

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### **BACKGROUND**

People in the United States may not be deprived of certain basic rights without due process of law. All government sponsored benefit programs, including Medicare, must provide people with meaningful notice and hearing rights if essential benefits are being withheld.

The Medicare HMO appeals process is used to resolve claims or service disputes, including cases when:

- the HMO has denied payment for out-of-plan emergency or urgent care services;
- the HMO member went out-of-plan for care when s/he could not obtain needed care within the HMO;
- the HMO member used non-HMO services because s/he was misled by HMO representatives about HMO membership "lock-in rules; and
- the HMO member wants to challenge the HMO's decision to deny medical treatment.

The Medicare HMO appeals process consists of five steps: Initial Determination; Reconsideration; Administrative Law Judge Hearing; Appeals Council; and Federal Court.

### **PROBLEMS WITH THE APPEALS PROCESS**

There are a number of problems with the HMO appeals process.

#### **HMO Enrollees Have Fewer Due Process Protections Than FFS Beneficiaries**

Hospitalized Medicare HMO enrollees do not have the same rights of immediate

appeal that exist in Medicare FFS if they believe they are being discharged prematurely.<sup>\*\*\*\*</sup> Also, FFS patients entering a skilled nursing facility have protections and appeal rights not afforded Medicare HMO enrollees.

### **HMO Enrollees Lack Basic Knowledge About The HMO Appeals Process**

The overwhelming majority of respondents to MAP's community and provider surveys stated that Medicare HMO enrollees are unaware of any right to challenge an HMO decision not to provide or pay for needed care. Often, HMO enrollees are not even given a written notice when a service is denied, let alone informed of their appeal rights (both of which are required by law).

### **The HMO Appeals Process is Unable To Address Situations In Which Access To Urgently Needed Care Is Denied**

If processed in a timely fashion, the first two steps in the appeals process can take as long as 144 days. This time frame makes it impossible for Medicare HMO enrollees to obtain immediate relief in cases where they have been denied medical care.

### **HMO Appeals are not Processed in a Timely Fashion**

The little data that exists on the HMO beneficiary appeals process indicate that large numbers of HMO appeals are improperly handled. Based on a review of HCFA's most recent on-site monitoring reports and data from Network Design Group (NDG), which contracts with HCFA to process reconsideration requests, MAP has found that there is systemic non-compliance with the mandated appeals time frames.

HCFA monitoring reports found that a number of the HMOs failed to accurately keep track of their appeal records; failed to provide enrollees with adequate information in their claims determination notices; and failed to provide coverage for certain types of out-of-plan claims, in violation of Medicare law.

The case of one of MAP's clients, Mr. K., illustrates the problems with the HMO appeals process:

Mr. K.'s HMO primary care physician first ordered cataract surgery in late 1989. However, the HMO never scheduled the surgery although promising to do so for almost two years. Finally, in April 1991, exasperated and no longer able to see, Mr. K. obtained the surgery out-of-plan. As a result of the surgery, Mr. K. could once again drive, read and function independently.

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<sup>\*\*\*\*</sup>Proposed federal regulations address this problem and, when finalized, will afford HMO enrollees with the same hospital discharge appeal rights that exist in Medicare FFS.

About June 1991, claims for the out-of-plan surgery were forwarded by Medicare to the HMO for payment. Mr. K.'s family tried to follow up many times with the HMO but were not able to obtain any determination on the claims. The first response Mr. K. received from the HMO was dated November 20, 1991. It stated that the HMO needed to investigate the claims. The HMO did not inform Mr. K's family of their appeal rights.

On February 4, 1992, the HMO informally advised MAP that it still needed to obtain its own medical records regarding Mr. K.'s condition. On February 26, 1992, the HMO advised Mr. K. that it was denying his claims as the services rendered "were elective and required prior authorization from the Plan. Although the surgery was recommended by an Opthomologist [sic], it was not considered urgent or emergent in nature." The letter further stated that the claims were being forwarded to NDG.

A telephone call to NDG on June 2nd to determine the status of its review revealed that the HMO had never forwarded Mr. K.'s claims to NDG. On June 16th, the HMO advised MAP that it did not have any information on Mr. K.'s claims other than one of Mr. K.'s letters reiterating his requests for payment, and that the HMO's denial was based upon that one letter. The HMO further advised that it had requested a copy of Mr. K.'s records from the hospital and that it would forward his claims to NDG when it received the information.

On August 17, 1992, 14 months after the claims were submitted to the HMO, the case was finally forwarded to NDG for its review.

Mr. K. eventually received care, but, if he loses his appeals, will have to pay thousands of dollars for the care. Moreover, the appeals system was useless in helping Mr. K obtain the care he needed. Mr. K. waited two years for his cataract surgery and might still be waiting had he not sought out-of-plan care.

## DATA

From an analysis of NDG overturned cases, between 1989 - 1991, UHP had more than double the number of overturned reconsideration cases per enrollee than the other HMOs in MAP's study (see Table 8).



**TABLE 8****NDG OVERTURNED HMO DENIALS PER 1000 ENROLLEES: 1989 - 1991**

HMO	1989 Per 1000 Enrollees	1990 Per 1000 Enrollees	1991 Per 1000 Enrollees	1989 - 91 Average
Aetna/Partners	.2	.5	.2	.3
Aetna N.CA	.8	.4	.2	.5
Bridgeway	.1	.7	0	.3
FHP	.9	.6	.3	.6
Inter Valley	.7	.1	.9	.6
Kaiser SCR	.1	.3	.2	.2
Pacificare/ Secure Horizons	.4	0	.1	.2
UHP	.6	1.3	2.0	1.3

Source: NDG, HCFA *HMO/CMP Reconsideration Special Report: Cases Overturned (Completely or Partially) for California HMOs, and Dollar Value of Services, by Month and Year of Decision, and Type of Service Contested*, Feb. 1992.

**DISCUSSION**

MAP and other organizations have found that beneficiaries, rather than wrestling with an ineffective and lengthy appeals system, simply disenroll and obtain care in the FFS Medicare system. This inability of beneficiaries to resolve quality of, and access to, care problems is harmful to the Medicare program as well as to individual beneficiaries.

HCFA encourages Medicare beneficiaries to enroll in HMOs as a means of saving money for the Medicare program. If beneficiaries who are unable to obtain needed care simply disenroll, then Medicare pays for their care in the FFS system.

The failure to provide expedited appeals in emergency situations, to adequately notify Medicare beneficiaries of their due process rights, and to process appeals in a timely manner are critical concerns which must be addressed if managed care systems are to cover the needs of enrollees.

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## SUMMARY AND CONCLUSION

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Medicare risk-contract HMOs are expanding throughout California and the nation. As more and more Medicare beneficiaries enroll in HMOs, organizations that represent Medicare beneficiaries and government agencies responsible for monitoring HMOs must look more closely at these organizations and how they provide care.

HMOs are an important alternative to the Medicare fee-for-service system. Their rapid growth in the Medicare market is testimony to their ability to provide high quality care at a substantial cost savings. Nevertheless, MAP believes that HMOs and the government agencies that monitor them can improve current protections for Medicare beneficiaries, many of whom are vulnerable because of age or disability.

The following conclusions are based on MAP's year-long study of Medicare HMOs in California.

### **HMO ISSUES**

Data presented in this study indicate that some HMOs can do more to prevent marketing, quality of care and due process problems.

#### **Failure to Protect Against Marketing Abuse**

Medicare beneficiaries are extremely vulnerable to misleading marketing by HMOs. MAP's case studies provide only a glimpse of the anxiety and financial distress suffered by Medicare beneficiaries improperly enrolled in Medicare HMOs.

HMOs generally provide accurate information in both their marketing materials and presentations. However, HMOs should do more to ensure that all marketing materials identify the organization as an HMO; indicate that non-senior disabled Medicare populations can join; and, when appropriate, translate materials into Spanish and other languages. HMOs should also ensure that marketing representatives do not exaggerate the beneficiary costs in the FFS system.

Commissions paid to marketing personnel for each new enrollee and lack of adequate

training and oversight of HMO marketing employees can lead to substantial in-home marketing abuse. Most of the Medicare HMOs in California had relatively low disenrollment rates, an indication that marketing abuse is not a problem in these plans. The study did find, however, that during the years 1989-1991, a few HMOs, most notably FHP and UHP, had excessively high disenrollment rates and marketing complaints.

Given the competitive nature of the HMO industry in California and the rapid expansion of Medicare HMOs to new areas of the state, the potential for future marketing abuse continues to exist.

### **Failure To Adequately Monitor the Quality of the Care Provided**

Risk-contract HMOs and their subcontracting providers have direct financial incentives to control the amount of health care, especially high-cost care, they provide their enrollees. Without adequate oversight, these incentives can lead to denial of needed medical services.

Anecdotal data indicate the need for additional scrutiny of HMO contracts with provider groups and of the referral process. Although anecdotal information may be of limited value, there is enough consistency in the various individual accounts presented here -- indicating that access to high-priced specialty and post-hospital services is more limited in HMOs than it is in FFS -- to conclude that additional study is needed.

Unfortunately, the disenrollment, utilization and complaint data presented in the study does not permit us to draw any firm conclusions about access to, and quality of, care provided by Medicare HMOs. Complaint data is collected haphazardly at best. The government does not collect, and the HMOs do not release, utilization data on a range of services.

Given the potential for underservice in the HMO system, HMOs must establish methods for assessing the quality of care provided by their contracting medical groups. Although some HMOs have such methods in place, others appear to provide little supervision and monitoring of contracting groups.

### **Failure to Ensure that Members' Due Process Rights are Enforced**

Without meaningful due process rights, federal requirements that HMOs provide all Medicare covered services and pay for emergency and out-of-area urgent care ring hollow. Unfortunately, this study's findings show that Medicare HMO enrollees have few meaningful appeal rights. Moreover, rights that do exist are often ignored, inadequately enforced and poorly understood.

The long and drawn-out HMO appeals system is especially ill-suited to help HMO enrollees who are at risk for adverse medical consequences resulting from a denial of

care. In these cases, the need for an expedited review process is obvious. Currently, when faced with an inability to obtain the medical care they believe necessary and denied adequate appeal rights, many Medicare beneficiaries simply disenroll from the HMO.

## **FEDERAL AND STATE OVERSIGHT OF HMOs**

Medicare risk-contract HMOs receive far more scrutiny from governmental agencies than do FFS providers. Given how little is done to protect FFS beneficiaries, some HMO supporters argue that increased oversight of Medicare risk-contract HMOs is unwarranted.

Nevertheless, as discussed throughout this study, the federal and state governments have an obligation to ensure that HMOs do not let financial incentives undermine access to, and quality of, care. The federal and state governments can and should do much more to ensure that HMO Medicare beneficiaries receive high quality care.

### **Inadequate Monitoring and Data Collection and Analysis**

Anecdotal data like that presented in the study, while informative, is of limited value as the basis upon which to draw conclusions. For that, we need hard statistical data. Unfortunately, little data exists with which to measure the quality of care provided by Medicare HMOs or to assess how well the appeals process works.

To supplement HCFA and DOC on-site monitoring visits and CMRI activities, additional data are critical. Inexplicably, HCFA and DOC manifest an almost cavalier attitude toward the collection of data that could be used to assess enrollment practices and quality of care.

No government oversight agency at either the federal or state level has made an effort to collect and analyze utilization data. Critical utilization data on a wide range of services, including skilled nursing admissions and days, home health visits, specialty care referrals, and rehabilitation services is not collected. Although HMOs have the capacity to provide this data, they do not make it available to the public.

In addition to utilization data, HCFA and DOC should pay greater attention to collecting and analyzing information on the HMOs' referral and appeals systems. The information in this study indicates that these systems do not adequately protect Medicare enrollees.

Finally, oversight agencies fail to provide information to HMO enrollees about their complaint systems or to effectively analyze the complaint data they do receive.



### **Failure To Address Systemic Problems**

HCFA and DOC attempt to address individual problems through a variety of mechanisms. Although these efforts may help the individual beneficiary with a problem, case-by-case assistance often does not get at the root of a problem.

On-site monitoring surveys and the complaint and disenrollment data that is collected often indicate that a particular HMO problem affects many enrollees. When this occurs, federal and state monitoring agencies should respond vigorously. However, this rarely happens; in the case of FHP's marketing abuse, it took three years for HCFA to move from reviewing the problem on an anecdotal, case-by-case basis, to compelling FHP to change its practices.

In their assessment of quality of care, government agencies have also virtually ignored the risk arrangements between HMOs and their subcontracting providers as a potential problem. Only in December 1992 did HCFA promulgate long overdue proposed regulations in this area.

Even when a problem is found, HCFA lacks sufficient enforcement options to ensure that HMOs respond to the problem. HCFA currently has little authority to impose penalties on contracting HMOs, short of contract termination or limiting new enrollment.

Finally, we need a better appeals system. An appeals process that provides expedited review when care is denied would protect beneficiaries at the same time as it would yield additional information on possible quality of care problems.<sup>\*\*\*\*\*</sup>

### **FAILURE TO PROVIDE MEDICARE BENEFICIARIES WITH ANY USEFUL HMO DATA**

Currently, the only information about HMOs given to Medicare beneficiaries comes from the HMOs themselves. Beneficiaries often ask "which HMO is best?" Unfortunately, they have no meaningful HMO comparison data available to them. To our knowledge, the information contained in this study is the first attempt by any government or non-profit agency to help Medicare beneficiaries compare and assess risk-contract HMOs.

Given the degree of difficulty MAP had in obtaining HCFA and DOC information, individual consumers are unlikely to possess the knowledge and resources to obtain HMO data on their own.

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<sup>\*\*\*\*\*</sup> Recent HCFA efforts to address marketing abuse and the agency's new on-site monitoring review guide are signs that the agency is more aware of some of the problems raised in this study and is taking some steps to address them.

MAP understands that much of the data analyzed in this study is problematic. Some might argue that, until improved, the data should not be released. However, the data is useful in that it provides a first attempt at quantifying Medicare HMO information for beneficiary use.

The release of data is a proactive way to address quality of care problems. MAP hopes that this report will inaugurate a more systematic attempt to collect and make public data on marketing, quality of care, and due process issues in all HMOs, not just those serving the Medicare population.

## **THE FUTURE OF MEDICARE HMOS**

Medicare HMOs and government organizations which monitor them must be more accountable to those they serve. All too often governmental policy makers look for a magic bullet to solve all of the nation's health care woes. Unfortunately, there are no magic bullets. HMOs and managed care may well be a part of the solution to the nation's health care crisis. However, if we are to move to a system of managed care for all Americans, we must look at how HMOs and their hybrids work, not only on paper, but in reality.

In the years to come, HMOs will loom large in the Medicare health care landscape. This delivery form has been shown to provide care of generally high quality to Medicare beneficiaries. Yet, from the information presented here, it also appears that some HMOs and their contracting medical groups may deny needed care to increase their profits.

MAP hopes that this report will encourage government agencies, the HMOs themselves and advocacy groups to work together to address problem areas and to ensure that, as this nation moves toward "managed competition," we focus our efforts on ensuring that the nation's most vulnerable populations receive appropriate, high quality medical care.

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## RECOMMENDATIONS

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The following recommendations are based on the study's conclusions that added protections are needed to ensure that Medicare HMO enrollees receive the medical care benefits to which they are entitled. Some of these recommendations can be achieved by the HMOs themselves. However, although self-monitoring and efforts by the HMOs to improve their operations benefit all concerned, HMOs need do no more than is required of them by law and by the regulatory agencies. Therefore, most of the following recommendations deal with what the regulatory agencies should do to address the concerns raised by this study.

Many of the recommendations that follow revolve around this study's central conclusion that there simply is not enough information about Medicare HMOs collected, analyzed and disseminated.

### RECOMMENDATIONS FOR HMOS

#### A. Marketing

- HMO literature should inform consumers of their right to report marketing problems to HCFA and DOC.
- HMOs should increase their training of marketing agents (and "ambassadors" if they are used) to ensure that they do not misrepresent the benefits of either FFS Medicare or HMO enrollment.
- HMOs should translate marketing materials into languages other than English for use in marketing to Medicare beneficiaries for whom English is not their primary language.
- All HMO survey and marketing materials should prominently state that non-senior Medicare beneficiaries are eligible to join.

#### B. Quality of Care

- HMOs that do not already do so should closely monitor the quality of care

provided by subcontracting medical groups through the use of chart reviews, utilization profiles, questionnaires to disenrolling HMO beneficiaries, and surveys of other providers such as home health agencies, hospital discharge planners and rehabilitation hospital staff.

- HMOs should review their own referral and authorization systems and those of their contracting medical groups to ensure that they do not restrict the provision of needed treatment.
- HMOs should provide Medicare beneficiaries with the option of obtaining out-of-plan second opinions.

### **C. Due Process**

- Each HMO should include in its referral process the services of a risk manager who, following expedited review, can override denials of care by the HMO or contracting medical group.
- Each HMO should institute procedures to ensure that it complies with applicable time limits for Medicare appeals.

## **RECOMMENDATIONS FOR FEDERAL AND STATE AGENCIES WITH HMO OVERSIGHT RESPONSIBILITY**

### **A. MARKETING**

#### **Marketing Materials**

- HCFA and DOC should collect and publish aggregate and HMO specific data on HMO enrollments/disenrollments, marketing problems and consumer complaints about HMO marketing.
- HCFA should require that all HMO marketing materials prominently state that non-senior Medicare beneficiaries are eligible to enroll.

#### **Marketing Practices**

- HCFA should prohibit in-home marketing.
- HCFA should establish training guidelines for HMO marketing programs.
- HCFA should limit the amount of a marketing agent's remuneration which can be based upon sales commissions and prohibit commissions for enrolling beneficiaries who disenroll within three months of HMO enrollment.



### **Marketing Oversight**

- HCFA and DOC should investigate all consumer marketing complaints and maintain statistics by HMO on them.
- HCFA should promulgate intermediate sanctions to address illegal or improper marketing practices.
- HCFA should rigorously enforce compliance with HMO marketing legal requirements.
- HCFA should have an independent person/organization verify on a random basis that new enrollees understand the major consequences (e.g., lock-in) of HMO enrollment.

## **B. QUALITY OF CARE**

### **Quality of Care Data Collection/Analysis/Publication**

- HCFA and/or DOC should require HMOs to provide utilization data per 1000 enrollees for hospital and nursing home admissions and days, home health visits, rehabilitation services, and primary care and specialty physician visits.
- HCFA and DOC should ensure that the HMO utilization data accurately reflects the HMOs' experience and that utilization data collection and reporting systems are standardized across HMOs.
- HCFA should develop a consistent classification system for collecting and analyzing beneficiary complaint data.
- HCFA, DOC and CMRI should inform beneficiaries of their right to bring quality of care problems to the attention of these agencies.
- DOC should develop a mechanism to analyze HMO complaints by type and by individual HMO and make better use of complaint data in quality of care assessments.
- CMRI should provide HCFA with non-aggregated medical record review findings for individual HMOs.
- On a yearly basis, HCFA should publish a comparison guide on Medicare HMOs, which includes information on utilization rates, complaint record, problems found in CMRI reviews, disenrollment rates by month in plan, and problems found in

HCFA on-site reviews (with HMO correction action taken).

- Congress should loosen restrictions on the publication of CMRI data.

### **Quality of Care Oversight**

- HCFA should study whether HMOs' prior authorization systems for referrals to specialty physicians, high cost procedures, elective surgery, and post-hospital care keep enrollees from obtaining needed treatment.
- During on-site monitoring reviews, HCFA should randomly survey HMO subcontracting providers, such as home health agencies and hospital discharge planners, about their quality of care concerns and the HMO's primary medical groups' referral processes.
- During on-site monitoring reviews, HCFA should examine all HMO utilization profiles of subcontracting medical groups.
- HCFA should finalize long overdue intermediate sanction regulations enabling the agency to impose appropriate penalties for HMOs that do not correct quality of care problems.
- HCFA should mandate PRO review of HMO quality assurance plans (QAPs).
- HCFA should give CMRI the ability to reduce oversight on HMOs found to provide high quality care based on a CMRI review of the QAP and other factors.
- DOC should conduct on-site reviews more frequently than once every five years, especially for non-Medicare HMOs that are not also reviewed by HCFA.

## **C. DUE PROCESS**

### **Due Process Data Collection/Analysis**

- HCFA should collect data from the HMOs regarding: the number and percentage of initial determinations and HMO reconsideration determinations that are at least partially favorable to the enrollee; the dollar amount and type of service involved in the claim; and the length of time taken for the decision.
- HCFA should collect and make public NDG data on the number of HMO appeals reviewed, the results of the appeals, and the length of time for each appeal at the NDG stage.

**Due Process Rights**

- HCFA should afford HMO Medicare enrollees with the same due process rights as in the FFS system, including nursing home appeal rights.
- HCFA should establish its own expedited review process independent of the HMO for cases in which the denial of care could result in harm to the enrollee. In these situations, the HCFA mandated review should be conducted within 48 hours.

**Due Process Oversight**

- HCFA should establish a time frame of no more than 60 days for NDG review.
- HCFA should issue intermediate sanctions, including monetary sanctions for HMOs failing to provide beneficiaries with legally required due process.
- HCFA should monitor HMO compliance with due process notice requirements.
- HCFA should make HMOs financially responsible for all claims for which the HMO fails to provide an enrollee with a written denial that includes information on how to appeal.

**D. OVERSIGHT AGENCIES' STAFFING/COOPERATION**

- HCFA, DOC, and CMRI should develop a means of sharing information monthly about HMO enrollment and quality of care problems and complaints and other issues of mutual concern.
- The federal and state governments should authorize additional funds for HCFA Regional staff, DOC and CMRI so that these agencies can increase their HMO oversight activities.

Mr. WAXMAN. Under the President's bill, the Medicare program remains a separate program with improvements such as the addition of a new prescription drug benefit and the home- and community-based services we discussed earlier today.

Since 1972, the Medicare program has relied on external organizations of locally practicing physicians and other health professionals to monitor the utilization and quality of services provided to beneficiaries. To date, no one has peer review organizations, PRO's. However, under the Clinton bill, the authority for the PRO program would be repealed once the quality reporting requirements for health plans were operational.

Unfortunately, I don't see what will replace current Medicare quality assurance efforts. I think the administration assumes that the quality program for private health plans will provide enough protection to Medicare beneficiaries. I would like to get your opinion about whether, assuming the PRO program is repealed, do you think there are adequate provisions to assure Medicare beneficiaries that the hospitals and doctors who provide care to them meet appropriate quality standards and can they get along with report cards that are issued by private plans even though most of them will not be enrolled in such plans?

Mr. BEE. I can speak to that, Mr. Chairman. I am a medical director for an HMO and I—our company is one of the first to be certified by NCQA as meeting all the standards for the HEDIS. But as a medical director, if I have 10 parameters to meet, I can be sure that I devote enough resources to meet those.

I think we need a plan that will, independently of what I want to do, look at everything that occurs in my plan, all patient encounters, and will keep me honest and also will show me things I can't easily find out for myself. I would like to know if a part of my plan is malfunctioning. If I can supply the data, I need an external body that can analyze that data and tell me how to improve the quality of what I provide.

Ms. DALLEK. My concern is with peer reviews, is that they don't have enough authority to monitor Medicare HMO's, not that they should be wiped out. I would like to see them given much more authority, and I specifically also would like to make sure that they can get some data, analyze that data and make it public. I am absolutely horrified at the inability of any monitoring oversight agency in the State or Federal Government to provide any information on Medicare or Medicaid HMO's to advocacy groups and to consumers. There is just no data out there, and that data that is there is proprietary and the HMO's will not give it to us.

At the PRO, prohibitions against releasing data are pretty draconian, and I would like to see some changes so that PRO's can monitor HMO's and then release the data to the public.

Mr. WAXMAN. Yes, Dr. O'Leary.

Mr. O'LEARY. I think probably the most critical thing that needs to happen is to make sure that the roles of the respective review groups are defined in a new quality overview framework. The kinds of things that accrediting bodies are doing and the PRO's are doing are changing, are changing fairly radically over time. We have recast our entire accreditation process, which covers all of the organizations in the mainstream delivery system, to focus on perform-



ance-based standards, patient center care, and the use of performance measures that address clinical and organizational issues.

For many years, I saw PRO's complement what we did as accrediting bodies. In other words, much of the review they looked at was practitioner-based information and they have more of an ongoing relationship to the organizations that they evaluated. We were more organization focused and more periodic in our review process.

The PRO program, as I understand it, is now increasingly going to be data driven, whether it is off of the UCDS or off of other databases, and it will increasingly be monitoring patterns of performance at the organization level. That makes what it does increasingly similar to what the accrediting bodies do. And I can certainly see complementary, but I would plead for some sorting out as to who is going to do what in order to provide the best service to the public.

Mr. WAXMAN. Yes, Ms. O'Kane.

Ms. O'KANE. I would urge—refer the committee to the report on the quality oversight of the Medicare program that was performed by the Institute of Medicine in 1990 which basically recommended that the PRO program be abolished.

However, I think that it would be kind of rash to abolish the PRO program until some kind of a substitute can be put in its place, because I do believe there is a need for quality oversight, particularly for the Medicare population. But I think that the approach that the PRO's have used in the past, which even they acknowledge is very flawed, incidentally it is one of the reasons that they can't publish the data, because it really is not reliable and there are—different doctors see different quality of care issues and so on. It just is inherently a strategy that will only find the bad apple and doesn't really improve the overall level of performance, but I do think that a strategy with accreditation, with performance measures, and we are admittedly at a very early stage of evolution there, and with member satisfaction information, and all of this incidentally, I believe, should be made available to the consumer and to advocacy groups that will be meeting to help consumers for the future.

Mr. WAXMAN. The IOM report that you referred to didn't simply say we should do away with the PRO's, but to also substitute something in its place.

Ms. O'KANE. Yes, it did. That is right, it did.

Mr. WAXMAN. Dr. Bee.

Mr. BEE. If I could speak once more for the PRO's.

Over the last 2 years, the PRO's in this country have been reengineering themselves in a major fashion. AMPRA itself is changing, considering training to consider a larger fraction of consumers. Across this country, particularly in California, in which the PRO's voted 2 weeks ago to totally restructure the governance of its active portion to include a majority of consumers, the PRO's are in the process of what they believe are largely educational organizations with strong linkages to the academic community.

For example, in California, Dean Phil Manning, who is sort of the dean emeritus of continuing medical education in this country, is a member of our master committee, actively involved in providing academic linkages with what we do with the data we analyze

and its feedback to the practicing community, which is what we believe will result in an overall improvement in the general curving quality in this country.

Mr. WAXMAN. I thank you all very much for those answers to those questions. You might have noticed bells ringing and all of that. That means we are being summoned to the House Floor for a vote. So we are going to recess just so long as it takes us to vote and we will come right back.

[Brief recess.]

Mr. WYDEN [presiding]. The subcommittee will come to order.

We thank you all for your patience and I want to particularly convey my thanks. We have worked with most of you on a variety of these quality issues and I think our concern is that it is terribly important that quality not get lost in this whole debate.

I think you all are well aware that on the issue of cost containment, there has just been oceans of news coverage and great attention, and somehow there has not been a whole lot said with respect to the issue of quality. My sense is that quality and cost containment go hand in hand. If you have people out there misdiagnosing the people's needs, or botching surgery, or in effect subjecting someone to an unwise drug therapy, you are going to end up spending a lot more down the road. So we are very interested in elevating the importance of these quality issues and really appreciate all the time that I think we have worked with each of you over the years on a variety of these issues.

Why don't we start with you, Dr. Bee, and I want to kind of skip around a little bit more in order of subjects rather than the order you testified in. I think each of you know that I intend to offer, when the bill comes up before the subcommittee, a comprehensive quality amendment to try to build on what is in place at this time.

Now, Dr. Bee, very appreciative of the excellent work you all are doing and very helpful to us, your program, to try to learn from what has happened with the PRO's. Why don't we start by having you give us your assessment of the regional foundations and the kinds of problems that you all have found with this kind of concept as it is contained in the administration bill.

Mr. BEE. One of our first concerns is that these represent a substantial conflict of interest. Academic medical centers have increasingly found that to pay their faculty salaries, they have to engage in the private practice of medicine, and I have contracts with three or four medical schools in my company to provide services. In one case, the medical school operates a formal IPA that has a contract for all levels of service in my company. Well, I think that puts an academic center in a position of some conflict of interest when it comes to doing quality review and surveillance and management.

On the other hand, the academic institutions are our bank of knowledge where we need to go repeatedly and often to look at what we do, to learn how to do it better. They are the people out there pushing the envelope of technology and treatment and assessing new ways of dealing with serious diseases. We need to be able to feed that back to the practicing community. AMPRA sees the health quality foundation as that link which looks at what is happening, analyzes the data, finds from that areas where improvement is necessary and needed, also areas of excellence.

We believe that health quality foundations have an important benchmarking role to find out what are the best standards to look to as a standard and to move on from there. We need the academic community.

Now, the PRO community has already strongly linked into the academic world. As I mentioned earlier, most of the PRO's have faculty from their local medical schools on their committees working with them to do the kind of quality assessment in feedback that is necessary. It is that feedback loop that we believe will change behavior, and a far more effective way than threats of some kind of punishment.

Mr. WYDEN. We will have some health quality questions—health quality foundation questions here in a moment.

Dr. O'Leary, you testified at a hearing before my subcommittee back in April 1991 that dealt with the question of the ambulatory surgery centers, a question of quality in those facilities that is growing at a very fast rate. You characterized the marketplace for ambulatory surgery at that time as, quote, "Dodge City before the marshals came," and you testified that about 14 percent of these surgery centers were accredited. The rest were essentially unsupervised. And over the years I have been very interested in trying to make sure that there was accreditation for these sites in which ambulatory surgery is performed, certainly those using anesthesia and programs that in effect paralyze the body's protective responses. Do you think it is essential to apply these kinds of minimum standards for ambulatory surgery centers still at this time?

Mr. O'LEARY. Well, I think all we are now looking at is the reorganization of what is already out there, and if anything, there is probably an even greater compelling need to look at these ambulatory sites than there was before because they will now be component parts of health plans and somebody has to look at them, whether it is the health plan itself or probably an objective outside body in some fashion, and I would note that since I testified before the committee, the number of ambulatory surgery centers alone has increased by over 33 percent, but the proportion of those that are subject to some surveillance has not increased, so be careful when you come to Dodge City.

Mr. WYDEN. I appreciate that answer because that is my sense. My sense is it is time to move beyond the minimum standards, and that is one of the reasons that we focused on the question of quality in this bill, is that we do want to accomplish now a great deal more than just compliance with the mere minimum standards.

Now, in the proposal that I am talking about in terms of amending the administration's bill, we would ensure that quality improvement actually takes place in hospitals, in health plans, and related organizations and would then extend the concept to the many freestanding surgery centers out there. They probably don't have the staff to undertake quality improvement studies at individual centers, but what would you think of the idea of requiring chains of such facilities to have a quality improvement program and then make them accountable to some independent entity, such as the consumers and AMPRA are calling for?

Mr. O'LEARY. Well, I think there are a lot of ways of grouping or aggregating responsibilities. I think you could see that quite nat-



urally in the context of a health plan which presumably would consist of a number of different kinds of ambulatory services.

One of the great advantages, at least in theory, of being part of a health plan are the economies of scale and using precious resources, such as those necessary to support quality improvement programs, data systems, and what have you.

I think we should all be—also be reminded that part and parcel of the ambulatory care systems are also literally doctors' offices, now increasingly as part of health plans, and the health plan will have an accountability for looking at those services as well.

Our experience, and I think the experience of others in reviewing services of this type, is that it is quite feasible to experience economies of scale if you—if the entity is willing to take responsibility for doing that. Now, this is the—you know, hence the importance of the term, in my view, of accountable health plans, accountable for doing exactly these things.

Mr. WYDEN. That makes sense and we are just concerned that those chains do have some accountability. We want to make sure we are not duplicating quality improvement efforts, but we want to ensure accountability.

Ms. Dallek, move to you for a moment. Your example of HCFA stopping the California PRO from following up on the cardiac surgery study would seem to be a real missed opportunity. State-wide quality improvement foundation, kind of concept we are talking about that Dr. Bee is talking about, could follow up on this kind of data and see if the problems were real.

I gather that the consumer movement and your organization specifically would support the kind of independent quality oversight that has been called for by Dr. Bee; is that correct?

Ms. DALLEK. Absolutely. HCFA didn't stop them from following up, but basically, when we showed that there was a 600 percent difference in our heart bypass operations between HMO "A" and HMO "B," we said, we want better data, we want to make sure this data is good, so HCFA, why don't you come and make sure that the hospitals are doing an accurate job of reporting and then we will know and we will analyze it and we will get better data next year? And instead, HCFA told the PRO, no, just don't bother with this data, it is not good.

It was the exact wrong response. You could have gone either way, but what they should have done is, let's make sure this data is good and then let's take a look at what the issues are and the problems there. I do support oversight, strong outside independent oversight by an independent entity.

Mr. WYDEN. Ms. O'Kane, let us move to you just for a moment. I share your view that managed care organizations ought to be accredited, particularly given some of the problems we have seen by what I call the hidden persuaders of health care, the underqualified utilization reviewers.

I guess the question that we have and we are trying to address in this proposal is what standards ought to be used. Now, you all promulgate some standards, a different set of standards for external utilization review companies from a group called URAC, and somebody affiliated with a PPO trade group, and then Dr. O'Leary's organization. I would be interested in taking the best of



these various standards and establishing a core set of requirements for these plans.

What would be your sense on that? Again, trying to make sure we use these resources, scarce resources for quality issues, the issues that seem to get lost so often in this debate, to make them stretch as far as possible?

Ms. O'KANE. Well, let me speak to the individual organization standards. Now, the Joint Commission standards, I have seen the latest draft of them and I know that there is another one that is coming out that is quite different so I won't comment on those.

The AAPI standards were not available to anyone outside of an organization that was getting accredited for a long time, so I have never laid eyes on those standards, so I have no idea what they are really about. I have heard speakers refer to what areas they looked at and so on, but I can't comment.

The URAC standards really were developed for a quite different purpose than assuring quality, and I think they really were more developed with the idea of reducing provider hassle, which is a noble cause, and I am not meaning to demean them, but we had a different purpose. Our purpose in writing our UR standards, and you know we go to five other areas besides UR, was to protect the patient from overaggressive UR or UR that wasn't based on current medical knowledge and to make sure that there are appeal mechanisms and so forth.

On the issue of taking a few from here and a few from there, I guess I don't think that is such a great thing unless there is a real heavy weighing of the quality of what goes into the pot in the first place. So I don't necessarily think that is the best approach.

Mr. WYDEN. Sure, Dr. Bee and then we will get Dr. O'Leary as well.

Mr. BEE. AMPRA and its organizations is not interested in the job of accrediting health care plans. You personally, and this committee and Congress, have invested or made sure that \$1 billion has been invested in the skill and techniques to do assessment across large databases of quality of care of patterns of care, and I think that is the answer to your question about the surgery centers.

A single health plan, as a health plan administrator, I can check the quality of a surgery center that I send patients to but it may be only 10 percent of its business and I don't know anything about what it does to the rest of its business, and society needs to know that. Consumers need to know that this is a good place to go. The only way we can find it out is if we have all payer data that is being analyzed by somebody without any financial objective whose primary objective is just quality management, quality improvement in the feedback loop.

Mr. WYDEN. Dr. O'Leary.

Mr. O'LEARY. Well, let me make a comment that goes back to my original testimony, and that is that your suggestion with which I agree presumes the creation or existence of Federal standards, for which there is no provision in the Health Security Act right now, but if—you know, if we make that assumption, then I think the way I would frame legislative language, to answer your question, would be to set forth the broad areas of performance in which you,

the Congress, would like to see standards, such as credentialing, or the management of information, or issues addressing over and underutilization, issues addressing continuity of care, so on and so forth. I suspect that Ms. O'Kane and I could agree on those performance areas in about 5 minutes, so there is not really a problematic issue.

And if you then charged some element in the Executive Branch with the responsibility for reviewing the crediting bodies who thought that they could match the Federal standards that would be created in these areas in the current statute, that would be the Secretary, but tomorrow it might be the National Health Board or the National Quality Management Council, but some entity would have to make a judgment that our program or NCQA's program or perhaps somebody else's program did or did not meet your requirements in this area. So it places the final judgment call on what, if you will, is the best or what meets your requirements in the Executive Branch where I personally believe that judgment belongs.

Mr. WYDEN. Let me ask a couple of questions now about the report card issue which generated so much attention. I think possibly it has generated so much attention because it is one of the few things that Americans have really gotten out of this. My 9 year old at one point said he wanted to see the report card on his doctor, so this issue is sinking in with the Barney crowd.

Now, Dr. Bee, let me start in this regard. I think that you all make a lot of sense in terms of advocating the focus on quality improvement for an independent oversight group. You all call them the, I guess, health quality foundations. We have been calling them the quality improvement foundations but we are talking about the same kind of thing.

Now, we have received some pretty solid advice that the same organization which works with practitioners on quality improvement should not simultaneously be involved in generating report cards that have caused the provider community a lot of anxiety. Does this at all concern you or is this a judgment that you don't share?

Mr. BEE. I think some of that concern comes from continuing medical education circles in which medical schools have been reluctant to try to tie its educational remedy to identifying poor practice, because that is an unsafe environment; practitioners don't want to expose themselves to that kind of risk.

As a practicing physician, I am not real anxious to have a glossy magazine put out in my community that lists my mortality for pneumonia or my therapeutic success with myocardial infarction or anything of that sort, and naturally I am not very excited about someone with access to all of the data generating that report.

As a health care consumer, I would sure like to have some of that information. I would really like to know who the best heart surgeon in my town is and I can't find that information out. In my role I can get some of it, but as a consumer of health care I really can't find that out.

I don't know how to resolve that debate. I think that it probably is not going to be resolved to everyone's satisfaction, certainly not to practicing physicians.

On the other hand, if we are satisfied that the data is fair and accurately collected, that it covers the full spectrum of what we do

and not an isolated little segment that identifies that really one bad day, then I think we would be much happier with sharing some of that information with the people who need our skills.

Mr. WYDEN. Now, one of the things that we have been hearing is that these quality improvement foundations could validate and critique and recommend changes in report card performance measures so that this kind of art that is in its infancy could be refined and improved. What would you think of that idea?

Mr. BEE. I think that is their best role. I think by looking at what is actually happening and comparing it to what our academic associates tell us should be happening, we can then make changes in behavior all across the spectrum of health care, including consumers. If people know that a certain course of action benefits their health, they are certainly much more likely to do it than if it is just a possibility.

Mr. WYDEN. One question for you, Ms. O'Kane, on the report card issue specifically. I gather that you think that this field is in such an early kind of infancy stage that nobody really knows what performance measures and information consumers want and that somehow or other this is really just sort of taking off in the dark. Ms. Dallek has testified today on behalf of some 25 national consumer organizations calling for lots of and pretty specific information. Now, is there any reason why we couldn't proceed with getting consumers this kind of information that they are asking for on the list?

Ms. O'KANE. Well, I don't mean to say that we don't have certain obvious types of information that—we have, in fact, a report card project right now which is going to be promulgating a prototype report card on 21 health plans.

What I am saying is that if these measures were developed by experts and many consumer organizations who really are sort of experts in their own right, and they should be because that is really their job, but if we are talking about the individual consumer who is trying to make a decision about which health plan to join, then I think we need to look at what their sort of utilities are in terms of what kind of information they find compelling.

For example, we ran our first focus group a few weeks ago and we discovered something that I actually don't find that surprising, which is that the consumers in this group said to us, we don't care what the immunization rate is in the health plan because—now this was a middle class group and we will be doing other groups—but we don't care because we know we will take our kids in and get them immunized. So there is a utility there for the regulator, and so report cards need to be thought about from both points of view.

What I am saying is that the people at the grassroots that are using these—that are going to use these to pick a health plan, we don't know how they are going to think about it, and that is what we are exploring at this point.

Mr. WYDEN. One of the things listening to the testimony, I think it would be great if you, Ms. Dallek, and you, Ms. O'Kane, kind of joined up in a little project and then you can report the results to Mr. Hash and Mr. Shulkey.

Ms. O'KANE. I would be delighted.



Mr. WYDEN. You can write the bill on the report card language, but that is very helpful and I appreciate it.

Dr. Bee.

Mr. BEE. My company recently spent a quarter million dollars asking its patients what they wanted from the health plan and what was important, and in many pages of this report there were many things listed, but almost none of them had anything to do with the quality of the medical care delivered. They weren't asking questions about outcome of pneumonia or hypertension or anything else. They were asking questions about will the doctor call me if I have an abnormal lab test, will the nurse let me talk to the doctor if I need to. So I think we—if we are going to educate patients on what constitutes medical quality, that is probably a different question than what is a health care plan that you would like to be with because it makes you feel good. We need to understand what people want and teach them what they should get.

Mr. WYDEN. Let's redo the project. So it is now Ms. Dallek, Dr. Bee, and then Ms. O'Kane because I could tell there was disagreement. Yes, Dr. Berenson?

Mr. BERENSON. I would just like for a moment—

Mr. WYDEN. You want to get in on the project, too?

Mr. BERENSON. Why not. My remarks actually, I want wanted to just reemphasize my remarks.

In my experience, the first thing patients really want to know are those structural elements of plans, how do I see my doctor, what are the restrictions on referrals. If I need a specialist, how do I get there, and that is the information that is not easily available right now, and so I think there is actually a complementary kind of activity. Let's at least provide that kind of information in a structured precise kind of way, as we do the research, and a lot of it will be research on real outcomes of care.

But we talked a lot about performs and outcomes and I think glossed over the fact that people don't know what they are picking in their health plans right now. The brochures are misleading. The advertising is misleading and I think we can require some very precise disclosure about how plans operate.

Ms. O'KANE. I would like to jump in and say that the people we have talked to—I have to admit I am making a lot of use out of these 14 people that we talked to, but they kept going back and hammering this point, you know, we don't know how the plan works, we didn't understand how it worked when we got, and so I think it is a very important point, and that is an area where we can have really quick progress. I don't think it is technologically difficult at all.

Mr. WYDEN. Dr. O'Leary?

Mr. O'LEARY. Let me just comment that I think if you asked every person in this room what their idea of a report card was, you would get as many different answers as there are people, and one of the problems is that you have—it is like sound bytes. You only have so many opportunities on a report card and you really have to carefully select your measures, because your consumers can only digest so much information per unit time, and this really is pretty high pay off sort of stuff. I mean, in the current environment, you



are—most of this information is being collected and digested by major employers.

We are now in the process of about to hand all of this off to the consumers and wish them good luck. So this is not a light issue. This is a pretty heavy issue and a lot of careful thought has to go into selecting the kind of information that really is going to be useful to consumers. Some of that information they know and some of it they need to be educated about.

Ms. DALLEK. Let me just add my two cents, if I may.

It is true that consumers don't have a lot of knowledge right now about how to compare report card measures, however, I don't want to sell them short. They learn a lot and they have learned a lot, and the common question they ask us when they are thinking about joining an HMO is, which one is best, and it may be that they don't want to digest 15 different measures, whether one HMO provides one-half the rehab visits as another HMO, for example, or something like that. They may not want to do that and they may not have the ability, but they certainly know to call up their Representatives, the agencies, and the groups, the advocacy community who do have expertise, and we can help do that, and if I had some good measures, I sure would tell them about what I thought which one was best. I don't have enough measures to make that assessment and we don't do that but I could tell them, you need to look at these five areas or these six areas, and there is a lot of information that consumers can understand, and I disagree that all they want to know is, well, how do I utilize the plan, because most of our enrollees finally have got that.

The marketing has definitely improved in Los Angeles after some disasters we had a couple of years ago, but they do ask us which one is best and they want to know that, and I agree we need to figure out how to tell them that but it is critical to get that information out. And I want to get it out now, not in 5 years because we will never have a perfect system, and believe me, if one HMO looks bad, they will fix it the following year if it is made public. If it is not made public, we don't see a lot of changes.

Mr. WYDEN. I think it is a very important point, and to me the big thrust of these data efforts and these disclosure efforts is basically to help focus consumer questions. The idea is not to take one of these things and it is the be all and end all, but you get one of these and it helps to focus your questions. If you call the Medicare advocacy project, if you call Dr. Bee, if you call any one of your organizations, frankly, that is the same thrust behind the efforts that are under way by myself and others to open the National Practitioner Data Bank. The idea is not that the National Practitioner Data Bank is going to be the be all and end all once you roll out this information, but people believe they have got a right to know, it is going to focus their questions, and we think in the vast majority of the instances what is going to happen in a report card or when the data bank is opened up is people are going to say, these are issues we want to know about. Then they are going to get on the phone and start making some calls, rather than just take the report card, take the disclosure from the data bank, say this is it, be all and end all and rush out the door.

Let me ask about just a couple of other areas, and I really appreciate your patience on this. Let me ask a couple of you about the point-of-service issue, which has gotten, you know, kind of controversial here in the last few weeks.

Ms. Dallek, you are probably aware that some of the HMO's seem to have made it a pretty high priority to get Congress to delete the requirement that all HMO's offer consumers a point-of-service option. Now, in my view, this provision will help ensure that the HMO's are accountable for the adequacy of their network. If they do a bad job signing up enough qualified OB-GYN's, for example, women aren't going to queue up for 6 weeks. They are going to go to their primary care elsewhere. Is that a view that you share in?

Ms. DALLEK. Absolutely. Let me give you an example of what goes on in Los Angeles with our HMO. Right now it is oftentimes difficult for them to even get a second opinion, although Medicare requires that HMO's provide a second opinion, because an HMO will sign up with a medical group, a subcontracting medical group, and let's say that subcontracting medical group has three ophthalmologists, all of them in partnership. Well, if you need a second opinion, you go to one ophthalmologist, the only place you can get your second opinion is from the partner. Well, that is not a real second opinion. If they could go outside the plan and get a second opinion, and we had one case where the woman did switch within the same HMO to a different group, got a second opinion and had her cataract surgery immediately.

And so there are not meaningful second opinions written into the Clinton plan. There is not meaningful second opinion ability within some HMO's now. And I sure think we need to have the ability to go outside the plan if you really are very concerned. You pay a little more but get that second opinion outside the plan and get—you will feel better, too, if you know you can get out. I think consumers really do want this. I think it is important.

Mr. WYDEN. Dr. Berenson, do you disagree with anything Ms. Dallek has said?

Mr. BERENSON. No. Actually I like point of service. That is what the market is moving to. The market is responding. I don't even mind having a requirement if it is a real point-of-service option. My concern was how the Clinton bill was drafted. It suggests, and I have been told it might even have been a mistake, but at least the current language, for certain services there is no cost sharing whatsoever staying in or going out, and so that provides really no control.

If it were a true point of service which has to involve significant cost sharing and a higher out-of-pocket maximum, I could certainly accept that. I do think actually the market is going to solve that problem. So my concerns were less with the concept and more with the specific language of the Clinton proposal.

Mr. WYDEN. That is helpful, and the staff seems to think you are right on that point. You know, the whole point is, and you may be aware that I was one who just sort of basically pounded on the table for this point-of-service option, because when the insurance industry started running these ridiculous junkie television commercials about how people didn't have freedom of choice and didn't get

to see who they wanted when they want, it struck me that the point-of-service option was the one thing that you could take out there across this country and say to people, look, those television commercials are just wrong, people getting to see who they want, when they want, under any circumstances, recognizing that if they go outside the network they are going to pay a little bit more.

Our sense was that not very many people would end up going outside the network in the good HMO's, good point-of-service plans, and we picked up some evidence in that regard and the managers of the plans have told me that they learn a lot about the adequacy of their own network by seeing what services people go out to receive.

So I am glad that there is a good feeling on this panel that this can be a useful management tool, and when we have got some of these HMO's beating the doors down saying that Western civilization is going to end because there is a point-of-service option, you know, mandatory offer, we are going to have your testimony on the record in that regard.

One last question for you, Dr. Berenson. It seems to us that there is a question of accountability of who is left holding the bag when an HMO constructs an inadequate network. The people who set it up? The people who had nothing to do with it? Who, in effect, gets stuck there?

Mr. BERENSON. Well, and I would support an accreditation process so you can't have an inadequate network. An HMO that had three ophthalmologists and they are all in the same practice to me would not qualify, and so I think I would support the notion that there is a certain guarantee that all HMO's have to meet, solvency requirements, quality requirements, et cetera. That is a given and it was beyond that level that I think there should be some pluralism and difference.

Mr. WYDEN. That is very helpful. The only other question I had for you, Dr. Berenson, are your thoughts between the relationship between physician incentive plans and quality. I think we would be especially interested in your thoughts with respect to how it might affect underutilization.

Mr. BERENSON. Yes, I actually wrote a few articles expressing great concern about individual capitation, primary care capitation with large risks. I have talked with the GAO people and others about that. And I honestly do not know how to—there probably are some kinds of incentive plans that are so far beyond the pale that you want to just eliminate them, but in all of these sort of research that has been done to date, looking at relationships between incentive plans and outcomes, it has been hard to find a direct relationship.

So until that emerges, I guess where I would be on that one is to be very precise about how these systems work. I think if you gave most consumers information that says we pay your doctor a capitation with this kind of risk, essentially rewarding him or her for not seeing you or taking care of you, many consumers would say that is not the kind of plan I wish to be in.

One could make the same kind of case about an unmitigated fee-for-service plan, which actually George Bernard Shaw was the one who has the famous quote, that he warns for political humanity



that gives the surgeon an incentive for taking a leg off but none for keeping it on.

I do not know how to define a proper kind of physician incentive system and one that is easily labeled beyond the pale. So I guess where I am on this is, if you actually provided the information, I think people would make the kinds of decisions that would penalize the plans that had too much primary care capitation, too much risk, et cetera.

Mr. WYDEN. Ms. Dallek, your thoughts on that?

Ms. DALLEK. I agree. I also don't—I think we don't know enough about these incentive arrangements. I am concerned about when physicians are totally at risk. I have just seen too much incentives to underserve but I don't know what we do on that. I would like to see some limits on risk but I don't know where those limits should be, but because of that I feel incredibly strongly that you need these other quality protections, including expedited appeal systems outside the plan. I just think there is a lot of other things we need to do to protect people against underservice and then start looking at these risk arrangements and publicizing.

I agree with Dr. Berenson, it is critical to publicize them. Get some information out there to consumers. Right now they have zero, zero information on which to make any kind of judgments.

Mr. WYDEN. Do you think—a couple other disclosure issues. Do you think that there should be disclosure of the relationship between doctors and the plans, Ms. Dallek?

Ms. DALLEK. Yes. You know, I am a consumer representative and I think you need a lot of disclosure and trust the consumer, trust their advocates and let us—right now we have none, and if we find at some point that there is too much or that it is not helpful or that it inappropriately penalizes some plans, you can change your mind. You can change systems. Things change all the time, but I am supportive of a lot of disclosure and that would be—one of them is relationships on who owns what.

Earlier I heard testimony from—Metzenbaum had testimony on the other side of a woman who didn't get her Pap smear read or her biopsies read—they were incorrectly read seven times or something in a Wisconsin HMO, I think it was, and the ownership of the lab, the guy that opened the lab was also on the board of directors of the HMO, and you need to have those protections against that kind of thing and you certainly need to get that information out if that exists.

Mr. WYDEN. And how about, I neglected to ask it, on the report card side, do you think there ought to be disclosure of the relationship between issuers of the report cards and the plans that they are issuing? Because we have seen somewhere it is sort of self-reporting. You probably heard some of the stories as well, including, I think at least one of my colleagues who gave considerable exposure to a report card and found out it wasn't done by a—exactly an independent source.

Ms. DALLEK. Absolutely, and I would not—I also think you can't trust plans without—in terms of giving the information without checking to make sure the information they are giving is valid and reliable. I know I sound pretty cynical but I really think that we



have seen enough problems that we know we need to make some—address some of the problems.

Mr. WYDEN. Dr. O'Leary?

Mr. O'LEARY. I will just take that one step further and raise questions as to whether reporting or issuing report cards by alliances do not also involve some conflict of interest? And if we want truly objective reporting, that ought to come from a truly objective source.

Mr. WYDEN. Dr. Berenson?

Mr. BERENSON. I did want to also say, however, there is going—there has got to be a lot of data requirement and it will be much more expensive to have it sent from the plan to a separate source who then can independently validate all of it. The SEC has been in the business for, I guess, 60 years of overseeing corporate financial statements and it is a crime to disclose inaccurate financial information. I think we should look at that kind of model.

There should be some kind of auditing, random checks. There should be some information that is collected centrally, but I think we should expect plans to provide data and if they—if there is some pattern of actually lying about the data, that is—that is overseen and that is a criminal action.

Mr. O'LEARY. All of those are audited financial reports by an objective, hopefully objective, third party. That is the kind of thing I am talking about.

Mr. WYDEN. I think, you know, it is kind of like some of your friends see it this way. Some of your friends see it this way. I agree with my friends. I think the point is, we want to make sure that there is disclosure. We think disclosure is the best antiseptic. We saw these health quality foundations, or whichever initial we end up using, Dr. Bee, doing some of this auditing.

Dr. Berenson's plan is, I think, a very good one, and that is that everyone ought to be careful about jacking up the cost of all this, and Dr. O'Leary said he wanted to be sure somebody independent was doing it, and you wanted to be sensitive to costs as well. So we will work with you all to refine that.

I guess the—let me just wrap up by way of saying what I think is important about what you all have brought to this discussion of quality, is a much more activist approach than is now in the administration's bill. What has concerned me about the administration's bill, and your point about the regional professional foundations was a good one, Dr. Bee, I think they are a conflict of interest, frankly. But the single biggest problem with what is in the bill is that mostly it seems like kind of a monitoring of paper in a kind of passive sort of exercise.

What we want is an independent process for trying to track these problem providers and then ensure that people go to the provider and to the plan and say, here is what the problem is, review the records, review the protocols, and, in effect, set in place a remedial kind of strategy to try to turn it around rather than spending everybody's time just going through wheelbarrows full of paper.

And you all have given us a much more activist vision of what it is going to take to improve quality and, to tell you the truth, I mean, the 85 percent of the American people who have coverage and are concerned how this whole thing is going to play out for

them, I think are going to feel very strongly about the kinds of things you are talking about, because it relates to the quality they are getting for the dollars they are now spending.

I hope you feel that this has been time well spent and it has been very helpful, I know, to the committee and to me.

Dr. Bee, did you want to add anything?

Mr. BEE. I just wanted to support what Dr. O'Leary had said. If you give us all payer, all encounter data, we can find out where these weaknesses are. We can find out the underserved patients and we can do something about it. And the linkage with the academic centers allows us to do just that feedback that you mentioned because we need to focus it on where there is a learning or knowledge deficit. We don't need to reeducate people about what they can already do well.

Mr. WYDEN. Excellent panel. Any of you have anything you would like to add further?

Ms. DALLEK. Just thank you.

Mr. WYDEN. The subcommittee is adjourned. Thank you.

[Whereupon, at 3:43 p.m., the subcommittee was adjourned, to reconvene at the call of the Chair.]



## HEALTH CARE REFORM

### Prescription Drug Benefit

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TUESDAY, FEBRUARY 8, 1994

HOUSE OF REPRESENTATIVES,  
COMMITTEE ON ENERGY AND COMMERCE,  
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT,  
*Washington, DC.*

The subcommittee met, pursuant to notice, at 10:20 a.m., in room 2123, Rayburn House Office Building; Hon. Henry A. Waxman (chairman) presiding.

Mr. WAXMAN. I want to welcome you to our subcommittee hearing. Today we will hear testimony about the drug benefit in the President's Health Care Plan. An outpatient prescription drug benefit is an essential component of any plan that provides basic health care coverage.

Under the President's bill, prescription drugs would be a part of the standard benefit package guaranteed to all Americans. By adding outpatient prescription drugs to the existing Medicare benefit, the President's plan would fill a gaping hole in that program.

The difficulty comes, of course, in paying for the benefit, and this task is made particularly difficult in the case of prescription drugs. During the 12 years between 1981 and 1993 manufacturer prices for prescription drugs rose 128 percent, more than 6 times the rate of general producer prices in this country.

Today, American citizens pay far more for the same drugs than citizens in other countries. As the report of the General Accounting Office that I released last week demonstrated, drug companies charge on the average 60 percent more for drugs in this country than in the United Kingdom. Half the drugs studied were twice as expensive in the UK and several cost between 5 and 17 times as much.

There is, however, some encouraging news with respect to drug prices. Hospitals and managed care organizations are successfully using drug formularies to control drug prices. Formularies allow these institutions to select among therapeutically equivalent drugs on the basis of price, and drug prices did slow down last year, although we have no way of knowing whether change reflects a strategy on the part of companies to moderate prices during the debate about health care legislation.

The Clinton plan appropriately relies on market forces to bring down drug prices where the market can work. However, there are three key areas where the market has not worked in the past and



where we should not expect it to work in the future. These demand our attention.

The first is the Medicare drug benefit. The President's plan gives the Secretary of HHS the authority to exclude a new drug from Medicare if it is too expensive. This is the same authority that managed care formularies have today. This is the same authority that would be included in negotiations using market forces. The plan also includes a 17 percent rebate which is similar to the rebate paid to the Veterans Administration and under the Medicaid program.

The second is the retail sector of the market for prescription drugs. Retail pharmacists cannot use formularies because they must stock the whole array of prescription drugs that a physician may prescribe. Retail pharmacists are essentially at the mercy of the price established by the drug companies. The President's plan would prohibit price discrimination against retailers, requiring that they get the same price if they purchase drugs under the same conditions as other buyers.

The third area that merits our attention is breakthrough drugs. This is the most difficult issue of all, because these are the drugs that dramatically improve the quality of life and save lives. These are the drugs that we want developed and we must continue to offer generous incentives to generate the substantial investment that is necessary to attract capital for research on breakthrough drugs.

Nevertheless, breakthrough drug prices have gone through the roof in recent years. Just 10 years ago \$1,000 was considered to be an exorbitant price for a prescription drug. Yet today \$10,000 per year is not unusual. In fact, we almost expect that an important new breakthrough drug will cost \$10,000.

If access to important drugs is to be guaranteed under national health care, as it should be, what will prevent companies from charging \$50,000 or even \$100,000 for these drugs? In fact, there is already one drug on the market that costs between \$50,000 and \$500,000 per patient per year.

The President's plan would establish a breakthrough drug committee which would review the prices of these drugs, but would have no authority to require that an excessive price be lowered. I do not know whether this is the best approach or whether it is sufficient, but I do believe that we must grapple with this issue if we are to address responsibility for the issue of cost containment of prescription drugs.

We look forward to the testimony of the witnesses today. Before calling on our witnesses, I want to recognize the distinguished ranking Republican member of the subcommittee, Mr. Bliley, for his comments.

Mr. BLILEY. Thank you, Mr. Chairman.

Today's hearing begins the home stretch in this subcommittee's marathon hearing schedule. I want to thank the distinguished chairman for the bipartisan tone which has characterized these hearings. Although we have dramatically different positions on health care reform, these hearings have been guided by reasoned debate and discussion of the most complicated issues any Congress has ever addressed.

I am sorry to say, Mr. Chairman, that the same cannot be said about the administration's approach to this debate. Although this administration is in its second year, it is treating the health care debate as a political campaign. Its legislative strategy appears to be run by political operatives and media manipulators from the administration's all-purpose crisis center, the War Room.

The administration appears to believe that it can succeed in the health care reform debate by threatening and intimidating the Nation's health insurers, pharmaceutical companies, physicians and hospitals, as well as conservative members of its own party. In fact, the administration appears to believe that health care reform should be conducted as a war rather than as a debate.

Initially the administration told outside groups that those who disagreed with the proposal would not have a place at the negotiating table. Now a leading Democratic Senator has publicly told the CEO of our Nation's largest insurance company that because he disagreed with the administration and dared to endorse the Cooper bill he has a 'special place in Hell reserved for him.'

We on this side of the aisle find such tactics and statements totally reprehensible and uncalled for. As the past week has shown, tactics of intimidation and threats not only don't work, but have the opposite effect.

Of course those in the pharmaceutical industry know all about the administration's intimidation tactics, because they were first practiced on that industry. Approximately 1 year ago the pharmaceutical industry was identified as the first target during the debate on the vaccine initiative in budget reconciliation. The administration stated that the health care system was being ripped off by price gouging drug companies. In the most outrageous and false propaganda statement, they said that the companies were attempting to profit at the expense of our children.

Well, as Senator Bumpers and other members of the President's party pointed out, the real explanation of the problem had to do with vaccine liability lawsuits that pushed up the cost of vaccines, the government's owned failed efforts to immunize the poor, and the failure by many parents to take advantage of free immunization programs. But truth took a back seat to propaganda and the administration had begun its war.

The principal theme that I have been continually emphasizing during these hearings has been rationing. Put simply, the Clinton health care plan's reliance on global budgets and price controls must lead to both rationing of medical services and the rationing of new breakthrough drugs and other types of medical technology.

I first used this chart on my right, your left, at a September 28 hearing where the First Lady testified. I pointed out to her that during the past 5 years, or the time period 1985-1991, the British nationalized health care system grew at an annualized per capita rate of 3.84 percentage points above inflation, and the Canadian single payer system grew at 3.58 percentage points above inflation. In contrast, the administration's CPI premium cap would have the United States limited to zero real growth and make us the slowest growing health care system in the world.

The question that I posed to the First Lady on September 28, 1993, was simply this. No socialized system of health care has ever

come close to limiting spending to the CPI, and in the case of Britain and Canada we are talking about systems that explicitly ration health care. How is the administration's plan going to limit the world's best health care system to zero real growth and expenditures when systems that ration care to their citizens have not remotely approached these spending limits?

During our hearings I have also posed the same question to the Secretary of HHS as well as other cabinet secretaries, assistant secretaries and OMB officials. Now, almost 5 months later, I am still waiting for an answer.

Now let us look at another type of rationing, the rationing of new breakthrough life saving drugs and other medical technology. Clearly the pharmaceutical industry has been singled out for special treatment in the Clinton bill. No other health care provider is subject to such an array of price controls, rebates and outright blacklisting. The goal of the administration is best summed up in a recent statement by Senator Pryor, who said, 'I guess I'm coming more to believe drugs should be regulated as a public utility.'

Let me just briefly list the provisions affecting the drug industry which would help transform them into a public utility: The CPI insurance premium cap; the Council on Breakthrough Drugs; the minimum 17 percent rebate on existing drugs; the negotiated rebate for new drugs; blacklisting of new drugs; prior authorization and generic substitution; and unitary pricing as a condition of Medicare participation.

We will explore each of these issues in detail during the hearing.

The Clinton health care plan will force almost all Americans into large bureaucratic HMO's which will be forced to severely manage care because of the Draconian global budget in the bill. As you will see momentarily in this newscast from Sacramento, Calif., some HMO's are already limiting access to today's breakthrough drugs. Let us closely view this news report. We will be looking at our own unfortunate future under the health care plan.

[Videotape shown.]

Mr. BLILEY. Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Bliley.

Mr. Wyden.

Mr. WYDEN. Thank you, Mr. Chairman. I appreciate all your good work.

Let me be brief. This is an area I have tried to focus on in my career in Congress and I think this is a very important hearing.

I think that it's important to reflect just for a quick moment on the history of drug prices over the last decade or so. I think we know in the early 1980's the pharmaceutical market really didn't work very well. We saw high price hikes and we saw them even in instances where a new product came on line that was essentially comparable to what was already in the marketplace.

During the late 1980's we started to see more competition. Buyers got to be more price sensitive, and frankly, I think many in the pharmaceutical sector began to understand that nobody wanted to be the poster child for health reform when the Congress marked up this legislation, and I think that also served to produce some price restraint for some products.



The question then becomes, where do we go from here in terms of a sensible pharmaceutical policy for our country?

I'm of the view that at present the marketplace for drugs and medical technology provides little objective information so that the government and private sector buyers can compare one product to another. My sense is across this country the hunger among buyers and the government is for a sensible policy so that there are incentives for products that are clinically superior to what is actually out there today and at the same time are more cost-effective.

When we mark up this legislation I intend to offer a proposal to create voluntary incentives to drug companies and technology companies and private sector developers of medical technology to bring to the government comparable information so that we will be in a position right at the outset of evaluating those products to see how they stack up relative to what is in the marketplace.

Mr. Chairman, I look forward to our hearing. We've got a number of areas to explore, including the question of current rebate policy. It's an important hearing because it gives us, in my view, a chance to set about making a very different approach to dealing with pharmaceuticals in the 1990's and the next century than we had through the 1980's.

I yield back.

Mr. WAXMAN. Thank you, Mr. Wyden.

Mr. McMillan.

Mr. McMILLAN. Thank you, Mr. Chairman.

This hearing today is the first and only opportunity this committee will have to examine the consequences of the Health Security Act on the pharmaceutical industry. This is a shame, because the issue deserves to be examined very closely before Congress considers legislation which could seriously jeopardize this industry's ability to create life saving and cost-effective pharmaceuticals.

I hope that during this hearing the members of the subcommittee can focus on the real issue, and that is this. This bill is going to be bad medicine for the American citizen.

I have said repeatedly that I would be willing to work with the administration and have sought to do so to craft real health care reform legislation, not one filled with price controls, billions of dollars in new and unnecessary taxes, huge government bureaucracies and concentration of power which currently don't exist.

Two days ago I had the chance to give the Republican response to the President's weekly radio address and I pointed out that if the President and the First Lady are really serious about getting health care reform out of this Congress, then it would require a bipartisan effort. We all know that. Bipartisanship grows from the center, not the extremes, and the Health Security Act is an extreme proposal insofar as pharmaceuticals are concerned.

The way the Health Security Act treats pharmaceuticals is just one more example of an extreme approach which will make it nearly impossible to hammer out a reasoned approach that will truly, as we would hope in this case, open the floodgates of innovation while allowing true competition. We should encourage innovation in an effort to drive down prices.

Here as in many other areas of the Health Security Act, the rhetoric is for so-called "managed competition" while the proposal is for



government control and concentration of decisionmaking in a very few hands.

Instead of looking at what the free market is doing and can do, the President in his proposal seeks to place price controls on pharmaceuticals, ignoring the fact that this will do nothing but dry up research and development in this country, resulting in higher drug prices and fewer and fewer innovations.

While the free market, unencumbered by the heavy hand of government, is forcing pharmaceutical companies to trim their margins and profits and lower prices because of market competition, the administration's plan would abandon that and turn this country into a giant formulary, if you will, where a government bureaucracy would set the price.

If we have learned anything from totalitarian systems where central planning sets the price of products, it is this. It doesn't work. It will result in rationing and less and less innovation which in the end will result in less and less health care for the people that it purports to benefit.

I don't think that anyone who will testify today believes that the current pharmaceutical market is working at optimum efficiency. I certainly don't. I am sure that everyone sees some need for change to make sure that everyone in our society has access to the pharmaceuticals they need at a price that they can afford and, as the gentleman from Oregon points out, have a full awareness of what their alternatives are. I think that is extremely important. Then the consumer and the providers get into the decisionmaking process.

Price fixing and coercion on the part of government is not the answer. Competition is. And not just competition among pharmaceutical producers and marketers. We're talking about a competitive marketplace of providers and citizens, purchasers of health care who are part of the decisionmaking process.

The administration's proposals not only would lessen competition among pharmaceutical makers, but it will eliminate competition through the concentration of decisionmaking in the whole provider system. So we will end up with a situation somewhat analogous to the Defense Department putting out bids for contracts, and we all know what that means. We don't get the best price; we don't have competitive products being offered in most cases, and we forgo true quality. It tends to force concentration both with respect to decisionmaking on prices and the area of innovation.

For those reasons, I think that we need to back up and take another look at this and come up with solutions that truly foster competition and not concentration, and I hope that our witnesses today will help shed light on this subject.

I thank the chairman and yield back the balance of my time.

Mr. WAXMAN. Thank you very much, Mr. McMillan.

Mr. Kreidler.

Mr. KREIDLER. Thank you, Mr. Chairman. Mr. Chairman, let me digress for a bit to the comments that were offered by the ranking minority member in relation to discipline within party structure. Let me assure him that as a Democrat I adhere to Will Rogers' old adage that 'I don't belong to an organized political party. I'm a Democrat.' Believe me, that type of retribution and discipline is

something that is sorely lacking among Democrats, not something that is a rule, let me assure him.

I found it interesting that we were looking at the statistics on health care inflation in the various industrialized nations, the chart that Mr. Bliley has brought out a number of times to show to the committee. I think it would be interesting if that same chart were ever to show what percentage of the gross domestic product of those countries was also expended.

I also wonder whether we could ever look at a budget that is so much higher than anybody else's budget and not think that we could find a fair amount of waste and abuse and fat in that budget so that we might bring that budget down. If we applied those rules to the Federal budget, I know that most of us would agree we could continue to provide a great deal of the service, if not all of it, and at the same time make significant reductions in the Federal budget.

I would have to assume that the same rule applies to health care expenditures, the \$1 trillion this country spends today.

I would also like to point out that the video that we saw about a drug to treat Alzheimer's is an interesting one. Because of the liver damage that can result from the use of that medication, I assume Mr. Bliley proposes that we should allow the use of this medication to treat Alzheimer's and at the same time mandate coverage of liver transplants because of the damage that results from the use of the medication. I think prudent use of new experimental medications is warranted.

But, Mr. Chairman, this is a hearing to explore one of the most contentious issues of the health care reform debate, which is how to pay for prescription drugs. I strongly favor prescription drug coverage in the benefit package. We want to guarantee this to all Americans. But we would be irresponsible to include drugs without some policies to keep costs under control, just as we need cost control policies for all the rest of the health care system.

So I don't think it is realistic to expect that drugs would be covered for whatever the manufacturer chooses to charge. At the same time, I am concerned about the very fragile biotechnology industry, which is where some of the most promising and exciting discoveries are happening. Unlike the traditional pharmaceutical firms, biotech companies don't have a lot of product on the market now to generate revenue for research. They need to get their money for research from investors and those investments carry a good deal of risk.

Biotechnology stock prices have dropped in the past year. One reason has been the fear of price controls that could depress profits.

I don't think anybody wants direct price controls for drug products or health care services in general, but no one should expect public or private plans to write a blank check either. That's why we should discuss the issue honestly, describe proposals accurately, stick to the facts, and avoid the kind of rhetoric that sheds more heat than light.

I look forward to the testimony that we are going to hear and I urge that all members look at it in a comparable way.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Kreidler.

Mr. Hastert.

Mr. HASTERT. Thank you, Mr. Chairman. I'm glad we are going to have the opportunity today to examine the impact of the Health Security Act and what that impact will have on Americans' access to prescription drugs.

Let me be frank. I have a serious concern about what that impact will be. I'm troubled by the vast authority given to the Secretary of HHS in this bill to limit which drugs Medicare beneficiaries will be able to purchase. I've talked to hundreds of seniors in my district about the issue of prescription drugs, and I assure you that when they asked for reform they did not want someone in Washington deciding which drugs their doctor can prescribe and the maximum number of pills per prescription or the number of refills.

Probably the scariest aspect of this proposal is the Secretary can actually refuse Medicare coverage for breakthrough drugs. Currently many seniors have medigap policies that pay for prescription drugs, but under the Health Security Act they wouldn't even be able to purchase such policies, so only the rich would be able to buy the new drugs.

Possibly even more disconcerting is the likelihood that under such a regime new drugs would not be developed. We've heard testimony in this subcommittee before about the risky nature of pharmaceutical research. Experts point out that for every drug that successfully reaches the market more than 1,000 others fail. Investors will calculate the additional risk under the Clinton regime, and if they know that the price and the availability of new drugs can be limited by someone in Washington, they will find other investments that can assure more return.

Already we have seen investors abandon their biotech industry. Less investment will result in less research, fewer clinical trials, and laying off scientists, and less research means fewer cures.

So for the millions of Americans who are waiting for a cure for breast cancer or AIDS or heart disease and other countless other diseases, they should look closely at how this proposal will impact promising research. I'm afraid that they will see their hopes lost in a web of bureaucracy and regulation.

I do look forward to the administration's testimony and exploring these issues in greater detail. I thank you, Mr. Chairman, for the time. I yield back.

Mr. WAXMAN. Thank you, Mr. Hastert.

Mr. Towns.

Mr. TOWNS. Thank you very much, Mr. Chairman. I would like to thank you for holding this hearing. This is an important hearing, particularly for the Nation's seniors who often have to choose between purchasing their medication and putting food on the table.

I do not want to see the seniors in this Nation doing without needed medication. The drug benefit under Medicare and the administration's proposals seeks to correct this problem. Pharmaceuticals should be covered by insurance just like other medical services and therapies. They not only alleviate illnesses, improve the quality of life and save lives, but they are often the cost-effective means of treating illness. By taking medicine for ulcers, hyper-



tension, high cholesterol, depression and other diseases, our citizens save health care dollars by shortening hospital stays and avoiding surgeries.

We are hopeful that further research will lead to new drug therapies to combat AIDS and eliminate cancer. But can we count on new drug innovations to continue if we overregulate the industry? Let me remind my colleagues that just last year it was American research that yielded the first drugs to aid sufferers of multiple sclerosis and cystic fibrosis. In fact, we are the world's leader in the development of new drugs. As you can see from the chart here, the United States is 43 percent, the European community 31 percent, and Japan 11 percent.

I think that when you look at all of the European communities combined, which have very regulated markets and are responsible for only 31 percent of new drug innovations, yet countries like Japan that are committed to investing in research and development are steadily increasing their market share in new medicines, I fear that pharmaceutical companies, both large and small, will simply have to curtail their level of investment and research and development of important new drugs if we impose regulatory negotiated drug price controls.

Just last week the biotechnology industry organizations surveyed showed that 62 percent of their members have indicated that they will reduce their cancer research if price controls are imposed.

Finally, let me say a word about me-too drug issues. The argument that the industry is just engaged in promoting and developing me-too drugs does not wash with sufferers of clinical depression, for there is no one magic bullet. Does it make sense when many ethnic groups respond very differently to various medications? This is what physicians are telling me all over this country.

Therefore, as we move forward with health care reform, I would caution against imposing regulations which undermine the research and development capabilities of American drug companies.

Mr. Chairman, let us move forward with our eyes open and our ears open, not closed. Thank you very much. I yield back.

Mr. WAXMAN. Thank you, Mr. Towns.

Mr. Upton.

Mr. UPTON. Thank you, Mr. Chairman.

We are here today to discuss prescription drugs and how they fit into the President's health care proposal. The pharmaceutical industry, like every other health care related industry, does need to be part of reform, but we must not forget the tremendous benefits of prescription drugs. Our pharmaceutical companies are world leaders. They provide much of the R&D that leads to the exploration of new frontiers in health care, and these breakthrough drugs do save lives and allow individuals, who were previously unable, to become productive members of society.

I am very, very fearful that certain provisions in the President's plan, particularly the Secretary's ability to limit Medicare beneficiaries' access to certain drugs, as we saw on the video, and to set new drug prices will in fact have a detrimental effect on the industry's ability to continue R&D efforts at their current pace.

I am sure that most everyone in this room is hopeful that in our lifetime we will see cures for AIDS, for Alzheimer's, cancer, diabe-



tes, and so many other diseases that unfortunately cut so many lives short. We are greatly reducing the chances of finding these cures if we drastically reduce the amount of research conducted by pharmaceutical companies.

I simply ask that my colleagues not overlook the benefits of pharmaceuticals when undertaking a cost-benefit analysis of prescription drugs. In addition to improving quality of life, it has been proven time and time again that they in fact are extremely cost-effective when compared to the alternatives.

I yield back the balance of my time.

Mr. WAXMAN. Thank you, Mr. Upton.

Mr. Greenwood.

Mr. GREENWOOD. No statement, Mr. Chairman.

Mr. WAXMAN. Mr. Moorhead.

Mr. MOORHEAD. Thank you, Mr. Chairman.

I want to welcome our panels this morning. This is a very, very important subject that we are taking up today. I notice we have a representative of the American Association of Retired Persons here today. They are the group that is probably going to be hurt more by this legislation than any other single group, because they are hoping to finance this legislation on the backs of Medicare, but also on the backs of our drug industry.

Mr. Ken Abramowitz testified a few weeks ago. He's a top Wall Street health analyst. He said if this legislation was adopted, half of the biotech companies in this country would be out of business within 4 or 5 years. The pharmaceuticals and the biotech companies are already having difficulty getting financing for new research and development. We have been making so much progress in research and development. Many diseases formerly would have taken the lives of the people that got them, and now they are being able to recover and live. I think this is what we want to happen.

We do feel that there are places in our health care system that could be improved, many areas that could be improved, but we don't want to do it on the backs of advancement in medical care for the people in the United States.

There was an interesting story told about the CEO of a German company about the recent impact of pharmaceutical cost containment there. His neighbor's dog became ill and was taken to a vet where the dog was given the latest antibiotic. Around the same time, a member of the neighbor's family also became ill. The doctor gave him a generic version of an old antibiotic. The dog got well quickly. The human took much longer.

We don't want this result to take place in the United States of America. We want the pharmaceuticals, the biotech people to be able to continue research and development and to develop new products that will advance the health of the people of this country.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you very much, Mr. Moorhead.

Mr. Paxson.

Mr. PAXON. Thank you very much, Mr. Chairman.

Mr. Chairman, I would like to thank you for holding this most important hearing. Based on the comments and campaigns waged on this issue over the past months and years, it certainly should be a most interesting hearing.

Mr. Chairman, the issues before us, before this committee and this Congress, will determine the future of the pharmaceutical industry, but even more importantly, will determine the impact on many parts of our economy and our community. For example, how much research and development will continue, the pricing mechanism of the results of the research and development, the value of pharmaceutical stocks which impact tens of millions of Americans' personal economic security, including many folks in my district and my community, and, of course, will impact upon tens of thousands, potentially hundreds of thousands of jobs across the country and in my district that are based on and allied with the pharmaceutical industry.

Mr. Chairman, this issues goes to the very heart of our personal lives and our families. Both of my parents have faced, in the past few years, life threatening illnesses. Their lives were saved, thank God, due to the advances in pharmaceutical discoveries and research and development of medical technologies, all of which could be impacted by the decisions this committee and this Congress make on this and other issues relating to health care.

The overriding issue, Mr. Chairman, is not about the benefits of pharmaceutical drugs but what the cost is and who profits, and most importantly, who regulates the industry. This hearing is important because we can hear from the CEO's themselves and from others today what effect the Clinton plan will have on the future of new drugs in the United States.

Frankly, many of us are getting tired of hearing the same old arguments from Washington that the pharmaceutical industry is greedy and that they are only out there making huge profits, and the latest argument is that the new drug prices are at 3 percent above the inflation rate and therefore the Federal Government should set drug prices. In the real world, the drug marketplace has changed dramatically, so much so that in the last 14 months pharmaceutical companies have been forced to lay off 30,000 employees. That does not sound to many of my constituents in meetings we've had recently like a robust industry.

Mr. Chairman, what we need is not government mandated price controls and blacklisting, but reforms that will assist the industry to enhance competition and ultimately bring down costs.

In conclusion, this committee room has and will continue to be used to inject competition in several industries as a way to improve the marketplace. For example, the electric and gas industries have been through these changes, and shortly telecommunications and cable will be visited with the same reform. If it's good enough for these other important sectors of the economy, why can't we take that same approach to the pharmaceutical and biotech industries.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Paxon.

Let me ask unanimous consent that all members who wish to insert an opening statement in the record be given the opportunity to do so. Without objection, that will be the order.

[The statements of Hon. Mike Synar, Hon. Frank Pallone, Jr, Hon. Gary A. Franks, and Hon. Pete Stark follow:]

## STATEMENT OF HON. MIKE SYNAR

Pharmaceuticals represent 7 percent of annual health spending in the United States. This seems negligible, and maybe as though it should not be the subject of health care reform. But to many Americans, drug costs are real and painful. As the Pharmaceutical Manufacturers Association will testify, the country spent \$289 billion on hospital costs, of which Americans paid \$10 billion. But of the \$56 billion Americans spent on prescription drugs, \$10 billion represented out-of-pocket expenses.

To Americans, the costs of prescription drugs, can preclude them from getting the treatment they need. I would like to read the letter I received from a constituent, Mr. James D. Summers, from Grove, Okla., into the record.

My wife and I are retired and we are 62 years of age, but not yet 65, and we have no insurance. We cannot afford any insurance. I take a medication called Axid. It is the same as Zantac and the prescription is \$72.50 per prescription per month. When I had it filled last week they said next time it would cost around \$80 or \$85. I cannot afford this medicine, but I have to have it to control my hiatus hernia.

Mr. Summers is rightly concerned with the price of a drug that the industry does not even consider especially expensive. To those who are wealthy or have extremely generous insurance coverage, paying for drugs such as Axid or Zantac at \$75 to \$95 a month might be fine. But we have an obligation to address the concerns of people who are paying for drugs out of their own pockets, because although drug prices may be small in proportion to the total health care bill, they affect people's daily lives and their financial stability.

## STATEMENT OF HON. FRANK PALLONE, JR.

Mr. Chairman I would like to thank you for scheduling this most important hearing today and I also comment you for the tremendous time and effort you have put into this subcommittee's hearing process on health care reform.

In recent weeks we have heard repeated statements that America does not have a health care crisis. We may have an insurance problem, according to some naysayers, but there is no crisis. Well, Mr. Chairman in the prescription drug area, we have a very serious insurance coverage problem. Over 1/4 of all Americans have no coverage for prescription drugs and for seniors, our population most dependent on prescription drugs, over 64 percent of their drug costs are paid out of their own pocket. Mr. Chairman, when millions of senior citizens and working men and women have to choose between buying life saving drug therapies and buying groceries, because Medicare or their private insurance does not cover prescription drugs, we most certainly have a prescription drug insurance crisis.

The President has taken a great stride forward in ending this coverage crisis by adding a prescription drug benefit to Medicare and by including prescription drug prescription drug coverage in the basic benefit package and I commend him for this. Any health reform we enact must provide better prescription drug coverage to all Americans. However, Mr. Chairman, in providing everyone access to important life saving and cost effective drug therapies, we must make sure that we do not kill the goose that laid the golden egg. The pharmaceutical industry has been a convenient scape goat for those who say that greedy businesses are responsible for our health problems and point to the excesses of the 1980's as an example.

It is true that the pharmaceutical industry did not make enough of an effort to control its own prices during the last decade. But without the U.S. pharmaceutical industry there would be no need for a prescription drug benefit, because we would have no significant prescription drugs available for consumers. Ninety percent of all drugs on the market today were developed privately by the pharmaceutical industry. The U.S. pharmaceutical and biotechnology industries have been two of the few shining lights in our global trade balance and they will be the industries that lead us into the 21st century—if we don't cut their legs out from under them.

Over the last few years, the pharmaceutical industry has made great efforts to get its own house in order. The annual rate of increase in the Bureau of Labor Statistics' Producer Price Index for prescription drugs has dropped by over half: from 9.5 percent in 1989 to 3.1 percent in the year ending with the second quarter of 1993. Some here in Washington have been quick to dismiss the industry's attempts to control prices, but Mr. Chairman, efforts to decrease price, recent cutbacks in the price government programs will pay for pharmaceuticals, and the new competitive environment for prescription drug sales has already begun to take its toll on the industry. Profits are down in most companies and over the last 2 years, major pharmaceutical companies have announced job reductions of over 30,000 employees.



Nowhere has the stagnation in the industry been felt more strongly than in my home State of New Jersey, which is the home to many major pharmaceutical companies. Recently I held a job fair in my district, and on a day when the entire Federal Government was closed because of ice and snow, over 500 of my constituents braved the elements in search of work. Without a strong and vital pharmaceutical industry, jobs in New Jersey will continue to be hard to come by.

The bottom line Mr. Chairman is that the average cost of research and development for a new drug marketed in the United States was \$359 million in 1990. When only about 1/3 of all drugs launched actually earn enough to cover their R&D cost, pharmaceutical and biotechnology companies must be able to earn a fair rate of return in order to continue the R&D needed to bring new drugs to market.

I look forward to working with you Mr. Chairman and the administration to make sure that whatever prescription drug policy we enact gives consumers access to affordable drug therapies and allows the industry to continue to thrive and bring new drugs to the market every year.

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#### STATEMENT OF HON. GARY A. FRANKS

Thank you, Mr. Chairman for holding today's hearing. Several of the administration's proposals such as including the power to blacklist new drugs, investigate and perhaps denounce drug prices and set binding global budgets all base themselves on unprecedented government interference with the competitive free market to regulate prescription drug prices at a time when market forces are working to pull the price of prescription drugs down.

The effect of government interference would be counterproductive and possibly damaging to the research and development side of the pharmaceutical industry. A cure for just one of many currently uncured diseases, such as Alzheimer's, cancer, AIDS, arthritis, would save billions of health care dollars a year out of the system. But with such stringent government control over the breakthrough drug market companies will be less likely to invest large amounts of capital necessary to discover such a cure.

Regulation of drug prices would be a particularly harmful effect of the Clinton health care plan because it would bias research towards low-risk products. The government tends to look at everything on a time continuum and has a difficult time understanding that science can't be put on a calendar schedule. Not many drugs have predictable financial performances, actually 3 out of 10 drugs on the market actually bring in a profit for the pharmaceutical that patent it.

The pharmaceutical market has already begun to change the way they price and sell their product to be more in line with the consumer price index. We should be looking ahead by helping the companies that are our best hope at finding a cure for discovering treating many of the diseases that are the most deadly to our society.

#### STATEMENT OF HON. FORTNEY H. (PETE) STARK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. Chairman, members of the committee, thank you for the opportunity to provide testimony to you and your committee.

Over the next several months, the Energy and Commerce and Ways and Means Committees will take another shot at adding a prescription drug benefit to the Medicare program. Elderly Americans cite the lack of a comprehensive prescription drug benefit as a major concern, and in response, the administration has proposed a prescription drug benefit under the Health Security Act.

Expanding Medicare to include a prescription drug benefit would be of tremendous benefit to Medicare recipients and would have the potential of lowering costs to other components of the Medicare program.

Today, a majority of elderly Americans lack coverage for prescription drugs. And for those Medicare beneficiaries who purchase a supplemental policy covering prescription drugs, their coverage is limited. The most comprehensive a "Medigap" policy has to offer—Plan J—has a 50 percent co-insurance requirement after the deductible is paid and has a maximum annual benefit of \$3,000. After the \$3,000 maximum benefit, the Medicare beneficiary is again on their own. This is not much in the way of protection. An annual supply of Cognex, which treats Alzheimer's disease, costs about \$10,000 per year—far exceeding the maximum Medigap benefit. Compounding the problem is the fact that many seniors take prescription drugs for multiple conditions simultaneously. It was hardly a surprise to learn the results of a recent Families USA survey—13 percent of elderly Americans forgo other basic needs such as food in order to pay for their prescription drugs.



But identifying the desire and need for prescription drug coverage does not mean that the Federal purse is wide open. Adding a prescription drug benefit to Medicare cannot mean that the drug manufacturers have free access to the Medicare till. A prescription drug benefit must be structured in such a way as to be affordable—affordable to beneficiaries and affordable to all of us who finance the Medicare program.

In the “good old days” of Medicare, Medicare reimbursed what was to be “usual, reasonable and customary.” In sum, this meant that what the providers charged, we paid. With the implementation of diagnostic related groups (DRG’s) in 1983 and the resource based relative value scale (RBRVS) in 1989, the good old days came to an end. This is no time to return to those days by creating an unchecked drug benefit.

But I hear once again the calls for a blank check. In response to the administration’s prescription drug proposal, the drug industry has sounded the alarm stating that they could not possibly survive if we place limits on the reimbursements for their products. Mr. Chairman, as you know so well, it is anticipated that the drug industry will receive billions in new revenues if a Medicare drug benefit is provided.

The most recent statistics from the Bureau of Labor Statistics showed that drug prices increased 15 times the rate of all other goods produced in the United States in 1993. Last week’s report of the GAO to you regarding prices in the United Kingdom mirrored earlier findings with respect to Canada in that prices charged U.S. consumers were significantly higher than that paid in other countries for the same products. But despite the tremendous overcharging that is going on, and the continued increases in prescription drug prices, I don’t anticipate we will move too hastily. With the Federal Government having invested \$10 billion per year for sometime now in this industry, it is in the Federal Government’s interest to proceed cautiously so as to make sure we do not damage our investment.

This industry has shown itself capable of putting its own interests in front of the Nation’s on many an occasion. I expect that this might be the case again this time around—although I wouldn’t mind being in error on this one. Thank you again Mr. Chairman for the chance to present testimony to this committee. I look forward to working with you on fashioning a Medicare prescription drug benefit that gives the American people the value they deserve for the money they expend.

Mr. WAXMAN. The witnesses on our first panel are Dr. Philip Lee, Assistant Secretary for Health, Department of Health and Human Services, and Dr. Helen Smits, Deputy Administrator of the Health Care Financing Administration, Department of Health and Human Services.

Dr. Lee has appeared before the subcommittee during several of its hearings on the President’s plan, and we welcome him back. This is Dr. Smits’ first appearance before us, and we are pleased to have her. She brings to us her role as deputy administrator of HCFA a distinguished background as a clinician and teaching hospital administrator. Dr. Smits, we are pleased to welcome you.

Your prepared statements will be in the record in full. We would like to ask you to limit the oral presentation to 5 minutes.

Dr. Lee.

#### **STATEMENTS OF PHILIP R. LEE, ASSISTANT SECRETARY FOR HEALTH, AND HELEN SMITS, DEPUTY ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Mr. LEE. Mr. Chairman, thank you for the opportunity to appear before the Subcommittee on Health and the Environment to discuss the prescription drug provisions contained in the President’s health security plan.

I will briefly review the statement. You have really covered the issue in the other comments very broadly, but let me just make a few points.

The most important purpose of the prescription drug benefit under the Health Security Act is to assure that a physician can prescribe the right drug for the right patient at the right time. This is a simple goal, but very important to the quality of care.

While the primary goal is obviously the quality of health care, this benefit must nonetheless be provided at a cost the country can afford and with adequate incentives to support the productive research into new drug discoveries which have been emphasized this morning in the comments by the members. The President's Health Security Act meets these goals.

I just want to describe briefly the prescription drug benefits contained in the Health Security Act and explain how the Act's market-based reforms will increase the amount of information available to consumers and will contain costs through increased competition. Dr. Smits will then address the provisions relating to the Medicare program.

Under the Health Security Act, as you pointed out, Mr. Chairman, drugs, biological products and insulin approved by FDA for their medically approved indications will be eligible for coverage under the prescription drug benefit of alliance-based health plans. In addition, these drugs are also covered for other medically accepted indications as defined in at least one of three nationally recognized prescription drug compendia or in peer reviewed medical literature identified by the Secretary.

Each health plan is allowed to design its own approach to assuring appropriate use and controlling costs in its prescription drug coverage. And while each plan must provide all medically necessary and appropriate care, the Act allows plans to use methods of managing a pharmaceutical benefit that they determine to be appropriate. These methods would include formularies, incentives for generic products, drug utilization review, and prior approval requirements.

The President's commitment to the country is to make prescription drugs available to all Americans at reasonable prices. So careful attention has been paid to assuring that appropriate measures are in place to contain costs.

For the under-65 prescription drug benefit, the President's plan relies primarily on private sector competitive price negotiating mechanisms and managed care efforts to contain prices.

The Health Security Act, in addition, will require drug manufacturers as a condition of participation in Medicare to provide pharmacists with access to discounts on similar terms and conditions to those available to large, institutional purchasers. This requirement will affect prices paid for all prescription drugs, not just those paid by Medicare.

As was noted, the one exception to the market-based approach is the so-called breakthrough drug provisions. When a new drug is approved that has no therapeutic alternative or that offers a substantial improvement over existing therapies, there is the possibility that the lack of market competition combined with guaranteed private sector insurance for every American could lead to pharmaceutical prices that are much higher than they would have been in the current health care system.

This problem will be addressed through the Advisory Council on Breakthrough Drugs called for in the President's plan. This council will review the price of new drugs offering significant advances over existing products. Based on this review, the council will report to the Secretary on the reasonableness of the product's price.

Once the Secretary has received the council's findings on the launch price of a breakthrough drug, she has the authority and responsibility to publish these findings for the general public through a notice in the Federal Register. This information should help health alliances and consumers make appropriate and cost-effective decisions.

In addition to the benefits and these strategies to contain prices and expenditures for prescription drugs, there are a number of other issues that relate to cost-effectiveness which I have described in my testimony.

We have initiated a number of actions, particularly through the Agency for Health Care Policy and Research, that focus on medical outcomes data that will help physicians understand the optimal uses of specific drug products.

We will expand the use of practice guidelines, such as those recently issued by the Agency for Health Care Policy and Research on depression and primary care and also on early treatment of HIV individuals.

The continuing medical education initiatives, expanded use of what in the past have been called patient package inserts to get effective information directly to patients on the proper use of prescription drug, drugs utilization review, and other approaches will foster the appropriate use of prescription drugs.

Better information about cost-effectiveness will be an important element in all of this, and we are working and will work with you all in moving this area forward.

The cost-effectiveness research, as it becomes more stable and predictable, I think may make it possible to discover and promote cost saving interventions in a manner that is not currently feasible. The Public Health Service will be very glad to work with this committee in identifying the types of efforts that may be feasible today and those that offer the most promise for future exploration.

I would now like to turn to Dr. Smits to review briefly the Medicare provisions.

Mr. WAXMAN. Thank you, Dr. Lee.

Dr. Smits.

#### STATEMENT OF HELEN SMITS

Ms. SMITS. Mr. Chairman, members of the committee, I am very pleased to be here to speak about the Medicare drug benefit.

If you ask the elderly what they want to change in Medicare, they always tell you that the most important new benefit they want is coverage of drugs. Nearly 60 percent of our beneficiaries have little or no drug coverage. Many of them face very painful choices about either filling prescriptions they need or going without the prescriptions and having money available for things like food and housing. Their buying power is being rapidly eroded by the rapid increase in the cost of drugs. This change is essential for them.



The Medicare drug benefit, like the general drug benefit, would cover all drugs, biological products and insulin approved by the FDA. Medicare beneficiaries would share, in the cost of the drug benefits, they would pay their part B premiums, and they would also pay co-pays, but there would be an annual limit of \$1,000 on expenses for drugs.

I would like to note that medigap policies would still be available; that is, the elderly who wish to plan their health care expenses would be able to purchase policies which would fill in that co-insurance.

The proposal goes well beyond simply making drugs available to the elderly. The plan includes a variety of measures based in many ways on our modern technology which would help make prescribing for the elderly work better and will keep costs affordable for all of us.

First of all, automated on-line pharmacy systems are now capable of telling a pharmacist who is filling a prescription, when that prescription was last filled, even if it was another pharmacist, and what other drugs the elderly individual is taking.

I can't resist telling you this anecdote since this particular provision means a lot to me personally. Not long ago I visited my elderly father in New York and at my stepmother's request reviewed the medications lined up on his shelf. I asked him how he took them, and he said, I take one pill out of each bottle every morning and this bottle I take another one in the afternoon.

In that line of bottles were two different prescriptions for digitalis from two different pharmacists. Fortunately, the most recent of those had only been filled 10 days ago. If he had continued to take one every morning, he would have become critically ill and could possibly have died. Fortunately, I happened to pay my visit to him at a point where we could still deal with it without any serious problems.

We need this kind of electronic information system made available to pharmacists. States that have done this with their Medicaid prescribing show modest but real savings of 4 to 6 percent when they have it, so that it is a very affordable arrangement.

The proposal would require manufacturers to pay rebates to Medicare. These are rebates that are similar to but not exactly identical with the Medicaid rebates. We've really listened to the manufacturers' concern, and we base the rebate on their average discount, not on their best price. If you give a really dramatic discount at a particular time because of some special relationship between the manufacturer and the purchaser, that's fine. It's your average discount that determines the size of the rebate.

The Secretary does have the right to negotiate the rebate on new drugs where there is no experience, but she would do that based on what else is available in that class of drugs, on confidential information provided by the manufacturer and maintained as confidential about the cost of manufacturing the drug. She could hold that she had been unable to negotiate a successful rebate and keep the drug off the Medicare list, but in fact we believe the exclusion would be extremely rare.

We think that this proposal with its various compendia of ways to save money is fair to drug manufacturers who will experience



significant increased revenues in aggregate from Medicare in the first 5 years of the program. We think it's fair to the elderly who will in a sense help to finance this program through other cuts in the Medicare program. We also think it's fair to the small pharmacist who will be able to remain in business, who will not be taken over by mail prescription programs, and who will be guaranteed a fair fee for filling drugs.

Mr. Chairman, this country has the resources to provide all Americans with decent health care and with drug coverage. We promised the elderly 25 years ago that we would give them health security, and drugs are now eroding that promise. I urge you very strongly as you work on this difficult and complicated bill to give consideration to the real needs of the elderly to change the way that they receive drugs.

Thank you very much.

[Testimony resumes on p. 558.]

[The prepared joint statement of Dr. Lee and Dr. Smits follows:]

## STATEMENT OF DR. PHILIP LEE AND DR. HELEN SMITS

Thank you, Mr. Chairman, for the opportunity to appear before the Subcommittee on Health and the Environment to discuss the prescription drug provisions contained in the President's Health Security Act.

Ensuring that our citizens have access to vital prescription drugs at reasonable cost has been one of the most vexing problems facing our health care system. Your dedication over the years, Mr. Chairman, to developing and promoting sound prescription drug policies makes it a particular pleasure to come before your Subcommittee to discuss this aspect of health care reform.

Early on, the President recognized that a national solution would have to be developed if all Americans are to get the quality medicines they need at a price they can afford. The President's Health Security Act does just that.

The most important purpose of the prescription drug benefit under the Health Security Act is to assure that a physician can prescribe the right drug for the right patient at the right time. That is a simple goal, yet it is very important to quality patient care. Under this plan, for the first time in this country, physicians will have that ability for all patients. And, it will have a very significant impact on the care of our citizens.

And while the primary goal obviously must be the quality of health care, this benefit must nonetheless be provided at a cost the country can afford, and with adequate incentives to support productive research into new drug discoveries. The President's Health Security Act meets all these goals.

Today, I will describe briefly the prescription drug benefits contained in the Health Security Act and explain how the Act's market-based reforms will increase the amount of information available to consumers and will contain costs through increased competition. Dr. Smits will then address the provisions relating to the Medicare program.

We all acknowledge that the cost of providing prescription drug coverage to all Americans is an issue deserving vigorous attention. I believe that a decade of experience in managed care plans will support the Administration's view that competing health plans can control the cost of prescription drugs just as well as they control the cost of other essential health services.

I would like to note at the outset that the prescription drug policies contained in the Health Security Act are the product of extensive collaboration with the Congress, advocates of children and older Americans, representatives of pharmacists, brand-name pharmaceutical manufacturers, biotechnology producers and generic drug makers, and private sector purchasers.

## **PRESCRIPTION DRUG COVERAGE IN THE COMPREHENSIVE BENEFIT PACKAGE**

Under the Health Security Act, drugs, biological products and insulin approved by FDA for their medically approved indications will be eligible for coverage under the prescription drug benefit of alliance-based health plans. In addition, these drugs are also covered for other medically accepted indications as defined in at least one of three nationally recognized prescription drug compendia or in peer reviewed medical literature identified by the Secretary of HHS.

Each health plan is allowed to design its own approach to assuring appropriate use and controlling costs in its prescription drug coverage. And, while each plan must provide all medically necessary and appropriate care, the Act allows them to use methods of managing a pharmaceutical benefit they determine to be appropriate. These methods could include formularies, incentives for generic products, drug utilization review, and prior-approval requirements.

### **Containing Pharmaceutical Prices**

The President's commitment to the country is to make prescription drugs available to all Americans at reasonable prices. So careful attention has been paid to assuring that appropriate measures are in place to contain drug costs.

For the under-65 prescription drug benefit, the President's plan relies primarily on private sector competitive price negotiating mechanisms and managed care efforts to contain prices.

By encouraging the current trend to managed care, the Health Security Act capitalizes on the price competition occurring in institutional settings. For example, hospitals and health maintenance organizations are employing in-house formularies to negotiate effectively with pharmaceutical manufacturers for significant price discounts. These same institutions and plans are promoting less expensive generic drugs whenever possible, and seeking out therapeutic substitutes that can treat patients effectively. In managed care, pharmacists play an active role in counseling individuals on safe and cost-effective alternatives; and patients themselves take a more active interest in the type and cost of drugs they take.

In addition, the Health Security Act will require drug manufacturers, as a condition of participation in Medicare, to provide pharmacists with access to discounts on similar terms and conditions to those available to large, institutional purchasers. This requirement will affect prices paid for all prescription drugs, not just those paid by Medicare.

The President has chosen to rely on competition where it is reasonable to expect that drug price competition can occur. When generic drugs or multiple products in the same therapeutic class are available, market forces can keep pharmaceutical expenditures within reasonable limits.

The one exception to this market-based approach is the so-called "breakthrough" drug. When a new drug is approved that has no therapeutic alternative, or that offers a substantial improvement over existing therapies, there is the possibility that the lack of market competition combined with guaranteed private health insurance for every American could lead to pharmaceutical prices that are much higher than they would be in the current health care system.

Drug coverage for all Americans could prove costly, even if prices are reasonable. But some new drugs have recently reached the market at a cost of \$50,000 to \$300,000 per patient per year. The American people need to know that the prices they pay bear a reasonable resemblance to the costs of research, development and production.

We will address this problem with the Advisory Council on Breakthrough Drugs called for in the President's plan. This Council will review the prices of new drugs offering significant advances over existing products. Based on this review, the Council will report to the Secretary on the reasonableness of a product's pricing.

The Council would base its determinations on prices of other drugs in the same therapeutic class, cost information supplied by the manufacturer, the prices charged for the drug in other industrial countries, the projected prescription volume, economies of scale, product stability, special manufacturing requirements and research costs. Also included are evaluations of cost-effectiveness relative to the cost of alternative course of treatment options, and improvements in quality of life offered by the new product.

Once the Secretary has received the Council's findings on the launch price of a breakthrough drug, she has the authority and responsibility to publish these findings for the general public through a notice in the Federal Register. This information should help health alliances and consumers make appropriate and cost-effective decisions.

Taken together with the explicit provisions contained in the Health Security Act to contain overall health costs, we believe market forces, enhanced with better information on new products, can control the growth in pharmaceutical prices, and can encourage innovative strategies for cost-effective drug expenditures.



## Continuing Efforts to Define and Provide Cost-Effective Benefits

Although the Health Security Act is comprehensive in providing drug benefits to all Americans including a viable cost containment strategy, it is not enough merely to focus on drug coverage and pricing. Therefore, beyond the coverage provisions are other strategies for providing appropriate health care that deserve further consideration in the context of today's discussion. These include ways to encourage:

- o an increased focus on medical outcomes data, to help physicians and patients understand the optimal ways of using specific drug products;
- o expanded use of practice guidelines, such as those recently issued by the Agency for Health Care Policy and Research on depression and primary care.
- o revised coverage guidelines such as outpatient treatments that might substitute for expensive inpatient care;
- o continuing medical education in clinical pharmacology, including pharmaco-economics, to help physicians find the most cost-effective therapies for their patients;
- o expanded use of what we in the past have called patient package inserts, to get effective information directly to patients on the proper way to use prescription drugs; and,
- o drug utilization review, to foster appropriate use of prescription drugs.

These and other strategies for encouraging proper use of outpatient prescription drugs are essential if we are going to preserve quality of care and keep health care costs reasonable. Let me take a moment to mention the most important and perhaps most promising of these strategies -- gathering and disseminating better cost-effectiveness data on a variety of medical treatments.

Better information about the cost-effectiveness of various medical interventions is absolutely essential to the future of the health care system in this country. And because the writing of a prescription is the single most common medical intervention, cost-effectiveness in the pharmaceutical area is especially important.

We need to know much more about which drugs, biologics, and medical devices work best for which patients, under what conditions, and at what cost. We also need to communicate that information to the clinical community as it is developed.

To some extent, this work is already underway. Within the Public Health Service, the Agency for Health Care Policy and Research (AHCPR) sponsors research through its Medical Treatment Effectiveness Program (MedTEP), which has sixteen pharmaceutical projects already underway including cost-effectiveness studies. These projects, as well as the projects under the Patient Outcomes Research Teams (PORTs), are part of a broader AHCPR emphasis on research, dissemination, practice guidelines, and data development to support cost-effective medical treatment. This June, AHCPR will sponsor its first national conference on drug cost-effectiveness, to help coordinate the efforts of various federal agencies involved in this field.

In addition, the Office of Disease Prevention and Health Promotion (ODPHP) has begun to look at drug therapies as part of their cost-effectiveness work in Clinical Preventive Services. Federal research is not limited to HHS, of course. The Department of Defense, for example, has a triservice center in Texas that has begun its own cost-effectiveness studies in an effort to streamline its own formularies and control pharmaceutical costs.

It is clear, however, that much more remains to be done in this area. The Administration is vitally interested in appropriate strategies to further strengthen the emphasis on cost-effectiveness research throughout the health care system and the translation of that research into quality health care. This applies particularly to pharmaceuticals and medical devices, where the economic and clinical aspects of new technologies are both so crucial to quality health care.

This need is particularly acute in the period when a new drug or device first enters the market. As the use of managed care techniques expands, promotional activities are likely to revolve around comparative claims to an ever-larger degree, and accurate cost-effectiveness information will be needed as the product is being launched, rather than years later.

As cost-effectiveness research becomes more stable and predictable, it may be possible to discover and promote cost-saving interventions in a manner not currently feasible. The Public Health Service would gladly work with you in identifying the types of efforts that may be feasible today and those that offer the most promise for future exploration.

Thank you for the opportunity to address coverage for outpatient prescription drugs under the comprehensive benefit package of the Health Security Act. Dr. Smits will now address the outpatient prescription drug benefit under Medicare.

## THE NEED FOR A MEDICARE PRESCRIPTION DRUG BENEFIT

The elderly use more prescription drugs than any other age group in the United States. Medicare beneficiaries purchase on average 15 prescription drugs each year compared with about 4 prescriptions per person per year for the under-65 population. However, beneficiaries with functional impairments use about 26 prescriptions each year, and those in poor health use over 31 prescriptions.

We know that the majority of Medicare beneficiaries lack adequate insurance coverage for prescription drugs. In 1989, the Congressional Budget Office estimated that only 40 percent of Medicare beneficiaries had adequate coverage for prescription drugs, while 60 percent had little or no coverage.

Approximately 30 percent of Medicare enrollees receive prescription drug coverage through retiree group health plans. However, current retirees could lose their coverage if former employers decide that it is too expensive to cover pharmaceuticals. And according to employee benefits experts, fewer and fewer firms are expected to offer future retirees health and drug coverage.

Furthermore, prescription drugs are not covered by the majority of individual Medigap policies. Only three of the ten standard Medigap plans provide prescription drug coverage. Only about 20 percent of Medigap policyholders obtain prescription drug coverage.

Public sources of outpatient prescription drug coverage, besides Medicare, include Medicaid and State pharmaceutical assistance programs. Together, these programs pay for only 12 percent of outpatient drug costs for the elderly. Medicaid covers the cost of prescription drugs for only 16 percent of the elderly who are poor or near poor. The remaining 84 percent - or 10 million - poor and near poor older Americans do not qualify for Medicaid and its prescription drug program. Some states have tried to respond to the growing need for prescription drug coverage among their elderly citizens. However, only ten states (New Jersey, Maine, Maryland, Delaware, Pennsylvania, Illinois, Rhode Island, Connecticut, New York, Vermont) have pharmaceutical assistance programs in place.

Because public and private coverage is limited, Medicare beneficiaries must pay for the majority of medications out-of-pocket. Over 60 percent of all elderly prescription drug costs are paid out-of-pocket, making it the primary source of payment for prescription drugs for those 65 and older. HCFA actuaries estimate that approximately 85 percent of beneficiaries used prescription drugs in 1992, at an average cost of \$604 per user.

And sadly enough, the drug purchasing power of beneficiaries is rapidly decreasing. Prescription drug prices are growing much more rapidly than the rest of the economy -- six times the rate of inflation since 1980. As a result, beneficiaries -- most of whom live on fixed incomes -- are forced to make difficult choices between prescription drugs and other needs. According to a 1992 survey by the American Association of Retired Persons, one of seven senior citizens responded that they have failed to fill a prescription because it was simply too expensive. About 10 percent said they had to cut back on necessary items such as food and heating oil to afford their medications.

By forgoing essential medications or modifying drug regimens, the elderly compromise their health and perhaps increase the likelihood that they will need more intensive health care in the future. Adding a prescription drug benefit to the Medicare program would help ensure that the elderly are able to afford the drugs prescribed by their physicians.

In addition, a prescription drug benefit would make the Medicare program consistent with the standard benefit package offered by all health care plans under the Health Security Act.

#### **PROVISIONS OF THE BENEFIT**

Under the President's plan, the Medicare outpatient prescription drug benefit would begin on January 1, 1996. Any Medicare beneficiary enrolled in the Part B program would automatically be covered for the new prescription drug benefit.

#### **Coverage**

The Medicare drug benefit would cover all labelled uses of drugs, biological products and insulin approved by the Food and Drug Administration. The off-label use of a drug would be covered if the use is listed in at least one of the three national compendia or other authoritative compendia identified by the Secretary; or based on guidance from the Secretary, the carrier approves the use based on evidence presented in peer reviewed medical literature approved by the Secretary.



### Quality Assurance

The President's proposal does not stop with simply making prescription drugs accessible to Medicare beneficiaries. We also want to ensure that beneficiaries will use prescription drugs safely. We are very concerned about current research indicating that inappropriate prescribing and dispensing practices may result in adverse drug reactions in the elderly. A recent RAND Corporation review estimated that more than 40 percent of prescriptions for those over age 65 are inappropriate. Some of this inappropriate prescribing may produce adverse reactions that may lead to drug-induced illness, hospitalization, and even death.

In response to these findings, our proposal includes quality assurance mechanisms that would lead to improvements in prescribing by physicians, dispensing by pharmacists, and ultimately, better safety for patients.

First, the Secretary will establish an education program to promote appropriate prescribing and dispensing of medications by physicians and pharmacists.

Second, pharmacists would be required to answer the questions of their Medicare customers to ensure that they know how to properly take their medications.

Third, our proposal authorizes the Secretary to establish both prospective and retrospective drug utilization review (DUR) programs if analysis suggests that this is the appropriate choice. Prospective DUR requires pharmacists to screen for drug therapy problems before each prescription is dispensed to a beneficiary. Prospective DUR would, for example, alert the pharmacist that a drug adversely interacts with other drugs taken by the beneficiary, is inappropriate given the medical condition of the patient, or duplicates the effect of drugs currently taken by the beneficiary. In addition, prospective DUR systems may also alert the pharmacist or claims processors to potential fraud and abuse situations.

Retrospective DUR is a screening process that would take place after the medication has been dispensed. This would identify patterns of gross overuse, inappropriate or medically unnecessary care, and fraud and abuse. If the medication prescribed or dispensed is determined to be inappropriate, some type of intervention, such as a letter or phone call directed at the physician or pharmacist, would be initiated by Medicare.

## Cost Sharing

The Medicare drug benefit would be provided to beneficiaries after they have met an annual drug deductible set at \$250 in 1996. As with other Part B benefits, beneficiary would pay a premium to fund 25 percent of Medicare's cost of the new drug benefit. Our most recent estimate is that the drug benefit would add \$9.00 per month to the Part B premium in 1996. Beneficiaries would also pay 20 percent coinsurance. However, unlike other Part B benefits, there would be an annual out-of-pocket limit, set at \$1,000 in 1996.

## Cost Containment

Our proposal recognizes the importance of cost containment provisions to ensure that the drug benefit would remain affordable to both beneficiaries and taxpayers. We have included several cost containment mechanisms - including a manufacturer's rebate program for brand name drugs, incentives to encourage the use of generic drugs, and prior approval programs.

Medicare would become the largest single purchaser of medications under this proposal. And as such Medicare deserves some level of discount - I don't think anyone would dispute that. One of our goals in crafting this new benefit was to contain prescription drug costs for the Medicare program while retaining adequate incentives for research and development. We believe we have achieved this goal in our drug rebate program.

Under the proposed Medicare drug benefit, basic rebates would guarantee Medicare a discount equal to the greater of 17 percent of the average price paid to the manufacturer by wholesalers for products to be distributed to the retail class of trade, or the difference between this average price to the retail class of trade and the price paid to manufacturers by non-retail, institutional purchasers such as hospitals and HMOs. Each manufacturer would be required to provide us with the retail and non-retail price for each drug product so that we can calculate the rebates owed to us.

In the case of excessively priced new drugs, the Secretary has the authority to negotiate a special rebate with the manufacturer in place of the basic rebate. Many times manufacturers have charged whatever the market would bear when pricing new drugs.

There is no particular formula for calculating the appropriate rebate for new drugs. Instead, the Secretary would carefully consider a number of factors including the prices of other drugs in the same therapeutic class, cost information supplied by the manufacturer, and prices of the drug in other industrialized countries. If an agreement could not be reached within six months, the Secretary would be able to exclude coverage of the

new drug under Medicare. However, the exclusion of a new drug from the Medicare program is expected to be a rare occurrence. In addition to the basic or special rebate for new drugs, manufacturers that increase the price of a drug faster than the rate of inflation would pay an additional rebate.

Incentives to encourage the use of generic drugs are also included in this plan because these drugs offer comparable quality at lower prices. Generic substitutes are generally much less expensive than the corresponding brand-name product. Consumers generally pay 30 to 50 percent less when an equivalent generic drug is dispensed instead of the brand-name version. Our proposals to promote generic substitution are consistent with state laws. All fifty states have some form of generic substitution laws to encourage the use of generic drugs.

Unless a brand name drug is specifically requested by the physician, Medicare would only pay the pharmacist the cost of the generic substitute - giving the pharmacist an incentive to dispense generic drugs. In addition, the Secretary could require physicians to obtain prior approval before prescribing brand name drugs if a generic substitute is available.

Finally, our proposal includes a prior approval program to minimize the inappropriate use of prescription drugs as well as ensure that medications are cost effective. Prior approval could be required for drugs that are subject to misuse or inappropriate use, brand name drugs with generic substitutes available, and new drugs for which the Secretary had not yet negotiated a special rebate.

#### **Payment**

All pharmacists receiving payment for services and drugs provided to beneficiaries must accept Medicare's payment as payment in full. In general, pharmacists would be paid their estimated acquisition cost (EAC) plus a dispensing fee. The Secretary would determine the EAC. The EAC could equal a percentage of the published Average Wholesale Price (AWP), or the Secretary could determine the EAC by surveying wholesalers or pharmacies. The EAC, however, could not be established at greater than 93 percent of the AWP. The dispensing fee would be set at \$5 per prescription and would be indexed to the Consumer Price Index. The dispensing fee compensates pharmacists for filling the prescription and answering the beneficiaries questions regarding medication usage.

## **IMPACT OF THE BENEFIT**

The Medicare drug benefit would not only assist beneficiaries in paying for needed medications, it would also increase pharmaceutical company and pharmacy sales and guarantee the federal government a fair discount as a major purchaser of pharmaceuticals.

### **Pharmaceutical Manufacturers**

Manufacturers would still see net increases in pharmaceutical revenues even after netting out rebates to HCFA. According to HCFA actuaries, the net increase to all drug manufacturers as a result of the Medicare outpatient prescription drug benefit alone, ranges from \$3.9 billion in 1996 to \$5.7 billion in 2000. Of this total, the net impact on brand name drug manufacturers ranges from \$2.6 billion in 1996 to \$4.0 billion in 2000. The net impact on generic manufacturers ranges from \$1.4 billion in 1996 to \$1.8 billion in 2000.

These estimates take into account our actuaries' projections for new drug sales among beneficiaries resulting from the benefit. This amount is reduced by the rebates that manufacturers would have to pay in order to have their drugs covered by Medicare. The figure is also increased by the projected Medicaid rebate amounts which would no longer have to be paid to Medicaid since recipients would enter state health alliances.

### **Pharmacists**

A new Medicare drug benefit would also result in increased sales for pharmacists. According to HCFA actuaries, the net increase to pharmacists as a result of the Medicare outpatient prescription drug benefit alone, ranges from \$ 2.3 billion in 1996 to \$3.1 billion in 2000. Equally important, the Medicare rebate program would take pharmacists out of the middle of drug pricing problems. Pharmacists would be paid for the drugs they dispense to beneficiaries, and only manufacturers would be required to pay rebates.

In addition, our proposal would guarantee retail pharmacists equal access to pharmaceutical discounts. The community pharmacy profession has charged that some discounts may be given to purchasers solely due to their class of trade status (e.g., hospitals, HMOs, etc.) rather than as a result of economic advantages these purchasers provide to manufacturers.



Pharmacists have long raised objections to this perceived market segregation. The Health Security Act explicitly prohibits this practice. Thus, if a purchasing group of retail pharmacists offers a manufacturer similar economic advantages (volume buying, prompt payment, formulary purchasing, single site delivery), that group of pharmacists would be entitled to similar discounts from the manufacturer.

#### **Federal Government**

Besides receiving a fair discount as one of the largest purchasers of pharmaceuticals in the world, the Federal government would greatly benefit from a Medicare prescription drug benefit because drug utilization review and other quality assurance mechanisms promise to safeguard quality and potentially reduce Medicare program costs.

#### **ADMINISTRATION OF THE NEW BENEFIT**

I know that there is concern about administering this new prescription drug benefit. I would point out that we have gained invaluable experience in developing and implementing the Medicaid prescription drug program. We can look with some pride at what we have accomplished with the States over the last 3 years in the Medicaid prescription drug rebate and DUR programs.

HCFA has a good track record with drug manufacturers and States in developing working relationships, establishing new data and reporting systems, and implementing billing and processing systems. We have worked together to create a rebate agreement that meets legal requirements, protects proprietary information, and preserves current market interactions. We have created mutually agreeable definitions and nomenclature to describe our working relationships. And we continue to develop a process for resolving the disputes that are bound to arise in such complex interactions. This would serve as a solid foundation for the administration of the new Medicare drug benefit.

The major challenge to the Medicare program, of course, is the enormous volume of claims that such a benefit would produce. A Medicare prescription drug benefit could produce about a billion additional claims annually, well above the total processed for all the rest of the Medicare program of 660 million claims. Such volume would be best handled by electronic on-line systems in pharmacies for drug utilization review and claims payment purposes.

While complex, an electronic drug claims processing system seems much more achievable now than 5 years ago, when we were working on the Medicare catastrophic drug benefit. Currently, Medicare leads the industry in electronic claims processing. Medicare is now developing a state-of-the-art Medicare transaction system that would consolidate the current 14 claims processing systems across the country into a single, uniform system at a limited number of sites. As our technological capability grows, it provides a systems infrastructure that would make Medicare more responsive, efficient and effective in our relationships with beneficiaries and providers, and facilitates the implementation of an electronic system for drugs claims processing and utilization review.

At the same time, the Act provides the Department of Health and Human Services and the Department of Justice additional tools to use in detecting, investigating and prosecuting fraud and abuse that may arise in the submission of electronic claims.

#### CONCLUSION

Mr. Chairman, this country has the resources to provide all Americans, including the elderly, with the health care services we need for everyone to live more productively and comfortably. The Medicare prescription drug benefit proposed in the Health Security Act is affordable and necessary to make more complete the promise of health security enacted over 25 years ago.

We look forward to continuing our work with you and the members of this Committee to enact this important benefit. We would be pleased to answer any questions.

Mr. WAXMAN. Thank you very much, Dr. Smits.

I want to start the questioning.

Dr. Lee, we heard a lot of my colleagues and others condemn the idea of price controls on prescription drugs. Does the President's plan authorize HHS or anybody else to impose price controls on prescription drugs?

Mr. LEE. No.

Mr. WAXMAN. Absolutely not?

Mr. LEE. No. The benefits are covered. The managed care plans negotiate with the manufacturers for the price of those drugs. That's a competitive approach and is not a government price control, in my view.

Mr. WAXMAN. You indicate in your testimony that the administration expects under national health care managed care plans will use these formularies and incentives to use generic products to control the costs of prescription drugs. Am I correct that this approach will allow the health plans to exclude FDA approved drugs from their coverage as long as they provide medically necessary care in the form of another equally effective drug?

Mr. LEE. That is correct.

Mr. WAXMAN. You note, correctly, I believe, that the one place where your market-based approach will not work is for breakthrough drugs, that is, one of a kind drugs that have a very important use in treating disease. Am I correct that formularies could not be used to exclude breakthrough drugs from coverage?

Mr. LEE. They could not be used to exclude those drugs.

Mr. WAXMAN. In other words, the plans must cover breakthrough drugs regardless of their price; is that correct?

Mr. LEE. I would say that is correct.

Mr. WAXMAN. Today it is not uncommon for a drug company to charge \$10,000 for a breakthrough drug. Just in the last year we have seen Bristol-Myers charge \$10,000 for the anticancer drug Taxol, Genentech charge \$10,000 per year for the cystic fibrosis drug Pulmozyme, and Berlex charge \$10,000 per year for the MS Betaseron drug. These are drugs that cost \$30,000 per year, and one drug, benzylase Ceredase, can cost as much as \$300,000 per year. Am I correct that if the President's plan is enacted into law Bristol-Myers, Genentech and Berlex could charge \$20,000 for the next breakthrough drug and the plans would have to purchase the drugs?

Mr. LEE. Yes, I think that is basically correct. Of course, with the Advisory Council on Breakthrough Drugs, it would review the factors that led to whatever price was established, and that information would be made available to the Secretary and would be published in the Federal Register. Nonetheless, they could not exclude that drug as I would interpret the Act.

Mr. WAXMAN. All they could do is get the information together and the Secretary could only comment on the reasonableness of the price, but then the drug would have to be paid for?

Mr. LEE. With respect to the under 65 population, that is correct, as I would interpret it.

Mr. WAXMAN. Dr. Smits, let's look at Medicare. The bill does not permit the Secretary to impose a Medicare formulary. If formularies are such a good way to interject competition into the

prescription drug market, can you tell us why the administration did not allow the Secretary to use this device in the Medicare program?

Ms. SMITS. We considered it very carefully and discussed it at some length with pharmacy groups and with manufacturers. I think the basic issue is that managing a national central formulary is a different business from managing one for a hospital or a health plan. The hospital I ran had an outstanding formulary, very tightly controlled, but frankly, we had a tight but effective exception process. If a physician wanted a drug, he knew which physician he had to talk to about getting that drug.

Mr. WAXMAN. So you decided because of those kinds of reasons not to have a national formulary and to exert the leverage of the Medicare program to bargain with the companies to get one drug as opposed to another?

Ms. SMITS. Right. A formulary sometimes arbitrarily excludes drugs when there are three or four that are similar and of equal quality, and I think the feeling was that that has a different implication nationally than it does for an individual plan.

Mr. WAXMAN. Under the President's bill the drug companies will pay the Federal Government a 17 percent rebate on the cost of prescription drugs. It's my understanding that this rebate applies when an elderly person pays the full price for a drug because he or she has not reached the \$250 deductible. Can you tell us why the rebate goes back to the government rather than to the consumer in the form of a price reduction?

Ms. SMITS. There are a variety of other price control provisions which would ensure that the pharmacist does charge the individual a reasonable price. That has to do with incentives to use generics where generics can be substituted, with limits on what the pharmacist charges, an acquisition price plus a prescribing fee, and with the requirement that the pharmacist must accept assignment. So there are price controls in there. It gets too complicated to try to give the rebate back in each prescription.

Mr. WAXMAN. Dr. Lee, there seems to be considerable uncertainty about the provision of the bill that gives the retail sector equal access to discounts on prescription drug prices. I intend to submit clarifying language to the administration and would like to get your comments for the record.

Mr. LEE. We would be very pleased to do that, Mr. Chairman.

Mr. WAXMAN. Thank you.

Mr. Bliley.

Mr. BLILEY. Thank you, Mr. Chairman.

The Medicare prescription drug benefit: Do you want Uncle Sam as your doctor?

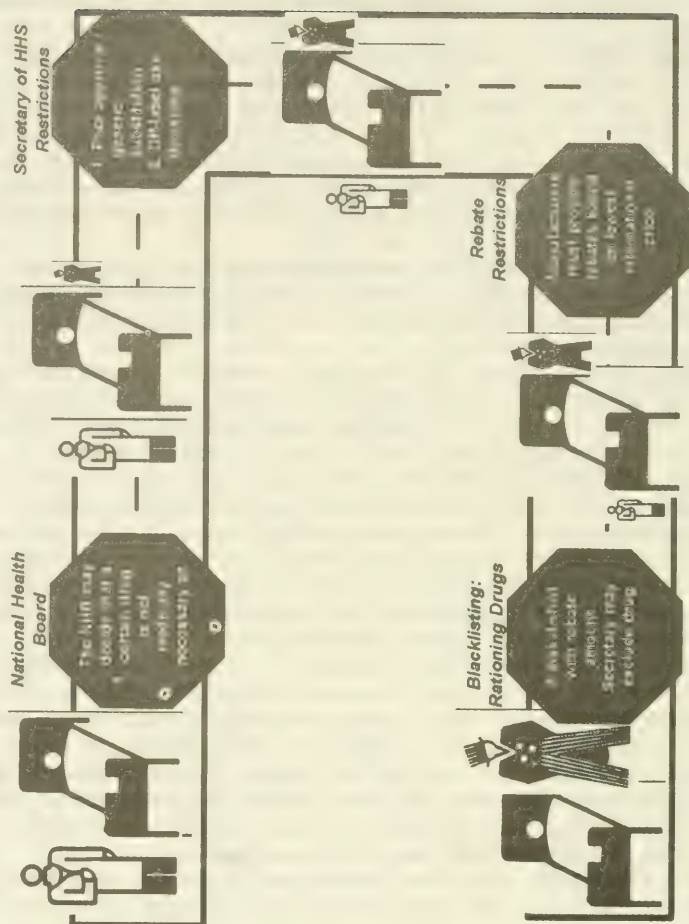
Mr. Chairman, I would ask unanimous consent to distribute a chart that I would like to discuss.

Mr. WAXMAN. Without objection, that will be the order.

[The chart referred to follows:]



# Medicare Prescription Drug Benefit: Do You Want Uncle Sam as Your Doctor?



Mr. BLILEY. Dr. Lee, as my earlier remarks have indicated, I am very concerned about the potential for the severe rationing of health care that I believe will occur under the Clinton health care plan.

I am also very concerned about the potential for the plan to allow government to insert itself in the doctor-patient relationship.

In my examination of the bill, I think the provisions that best illustrate why I have these concerns about our future under the Clinton health care reform bill are those concerning the Medicare prescription drug benefit.

Dr. Lee, you have stated that 'the most important purpose of the President's prescription drug benefit is to assure that a physician can prescribe the right drug for the right patient at the right time.' Let's walk with our doctor and patient through these stop signs or, as Ira Magaziner would say, toll gates, and see if the doctor-patient relationship is still intact after this long and tortuous journey.

First, the National Health Board may decide that a certain drug a doctor wishes to prescribe for his patient is not medically necessary or appropriate and thus would not be covered. This is the same National Health Board that Secretary Shalala described to this committee as a minor oversight body with some function.

In any case, this board that the administration is so anxious to sell to the public as possessing virtually no power has the power to override the decision of a doctor to prescribe a particular drug to his patient.

Second, if the doctor and patient make it past the National Health Board, then they have to deal with restrictions which can be imposed by the Secretary of Health and Human Services that are outlined in section 2002 of the bill.

The language of the bill is quite clear. The Secretary has full authority to require advance approval by the Federal Government about whether a Medicare beneficiary will be covered for a drug that the beneficiary's doctor has already decided is appropriate. This prior approval section will function like a formulary. In fact, this section gives the Secretary explicit authority for generic substitution for brand name drugs. Should the doctor prescribe a drug for an off-label use, which is a well accepted medical practice, the Secretary also has full authority to override that decision.

Third, there are rebate requirements on any manufacturer that wishes to sell its drugs to Medicare beneficiaries. The most interesting one allows the Secretary to require rebates based on the lowest price for new breakthrough drugs marketed after June 1993 on a specific list of western countries. This will hold the U.S. price hostage to the lowest price in any 1 of 21 countries, and we are talking about countries like Portugal and Spain where the standard of living is half that of the United States.

Four, but we are not finished. If the doctor and patient make it this far in their journey to provide the patient with a prescription drug, they still have to travel through the stop sign containing section 2003, which permits the Secretary to blacklist from coverage under the Medicare drug benefit any drug marketed after June 1993 where the Secretary feels she has not been able to negotiate a good price. This provision clearly gives the Secretary the author-

ity to deny important breakthrough drugs to senior citizens because of their price.

As we can see by this time, the doctor and the doctor-patient relationship has been replaced by Uncle Sam. Is this what our senior citizens want? These provisions explicitly ration the access of our senior citizens to new breakthrough drugs.

Dr. Lee, could you please comment on the chart?

Mr. LEE. I would like to ask Dr. Smits because of her direct responsibility for Medicare to respond, and then I have a comment on the National Board.

Mr. BLILEY. Fine. No problem.

Ms. SMITS. First of all, we have never suggested that every drug would be subject to prior approval. You might put prior approval in place with unusually costly drugs or drugs where there was documented reason to suspect overuse.

Off-label use decisions are based on best practice. That is, an off-label use is acceptable if it appears in one of the national compendia or if there is good peer reviewed literature. That's a very difficult area, and we have tried to strike a balance, but once there is good evidence that off-label use is appropriate, that is when doctors begin prescribing it. That would be acceptable. They would not have to go through any extra hoops.

Mr. BLILEY. But the Secretary would have the authority to override that.

Ms. SMITS. In terms of off-label use, the bill spells out quite specifically what the rules of the game are once the use has been reported appropriately in peer-reviews.

Mr. BLILEY. It may be clear to you but it's not to me.

Ms. SMITS. We would be very happy to work with you on clarifying language.

Mr. BLILEY. Thank you.

Ms. SMITS. On the rebates, the only situation where international price is taken into account is on the cost of a new drug. The rest of the time the rebates are based on American prices that the manufacturer has negotiated with American purchasers, not on foreign prices.

Finally, the only situation in which the Secretary may fully exclude a drug from Medicare is when she has been unable to negotiate a satisfactory rebate on a new drug.

So I do not believe that the Medicare provisions are unduly restrictive.

Mr. LEE. Just to comment on the National Board, the law specifies what drugs will be covered. Dr. Smits has noted that, and I have noted that in my testimony. The National Board's responsibility is to make sure that the plans implement the law in an appropriate fashion. It doesn't then restrict the benefits, but rather assures uniformity of application of the benefit package across the plans. So I do not see that as a restrictive provision with respect to the National Board.

Mr. BLILEY. But the National Board does have the authority to establish what is necessarily appropriate.

Mr. LEE. No. The Food and Drug Administration approves a drug for safety and effectiveness. The plan itself decides in the particular case, using a formulary if they wish to, and as we pointed out



in our conversation, they cannot exclude a drug that is medically necessary and appropriate where there is no equivalent drug available.

Mr. BLILEY. But they define what is medically necessary and appropriate.

Mr. LEE. What is medically necessary and appropriate is the generic definition in the legislation with respect to the benefits in the plan, that they are medically necessary and appropriate.

Mr. BLILEY. What I'm reading is at page 91, right at the top of the page, that an item or service that the National Health Board may determine is not medically necessary or appropriate in a regulation promulgated under section 1154.

Thank you, Mr. Chairman.

Mr. LEE. In that broad sense they have that authority, but with respect to prescription drugs, I think we have a lot of provisions that provide protections with respect to that.

Mr. WAXMAN. Thank you, Mr. Bliley.

Mr. Wyden.

Mr. WYDEN. Thank you, Mr. Chairman.

Dr. Lee, as you and I have discussed, what I think America really needs in the pharmaceutical area now, and I think this is true all the way from the consumer to the buyers, the HMO's and the insurance companies, is to know how the new products stack up against the old products, particularly in two respects. Are the new products cheaper than the products that are already out there and are the new products better than what is already out there?

It seems to me you all have in the President's budget an excellent proposal in terms of medical effectiveness research, but my own sense is even if the appropriations committee gave you every dime of what you needed, there is a big gap between what we need to get out to the American people in terms of comparative price information and comparative quality information. There is a big gap between what the government can do and what the people need. Would you agree with that?

Mr. LEE. I think what we are proposing in the plan provides a mechanism to do that through the purchasing by the plans, competitive bidding by the pharmaceutical manufacturers. Clearly the plans are already demanding that sort of information from the manufactures. We don't have that fully available, but I would say that there is a great deal of progress currently being made on the part of the manufactures in providing that information. Also on the part of the plans. But we do not have that as a requirement, as you know.

Mr. WYDEN. You are satisfied with the kind of information you are getting from the private sector on the quality of various kinds of pharmaceuticals and the cost-effectiveness? When I meet with the buyers, the health maintenance organizations and others, they tell me they are getting very little in the way of good objective information.

Mr. LEE. I would say we are not satisfied at the present time, but I think that there has been a good deal of progress made, particularly in recent years as we have moved more towards managed competition approaches and this kind of more prudent buying on



the part of large plans, although I don't think any of us are satisfied yet that that information is fully available.

Mr. WYDEN. Do you think it makes sense for the Congress to try to encourage early in a product's life private sector research which would give us good objective information on the comparative value of these products?

Mr. LEE. I think to the extent that that is feasible. I think it is not a simple thing to do, but I think that if we can encourage them to do that, it would be a good idea.

Mr. WYDEN. The FDA is supposed to keep up with drug company marketing claims of superiority for their products. I'm interested as part of my proposal in getting FDA and drug companies talking early about the appropriate design of studies that will provide sound comparative data for insurers and clinicians while minimizing the likelihood that FDA has to play a game of regulatory catch-up ball to stop exaggerated claims from being made. Does this kind of approach seem to have some merit to you?

Mr. LEE. Yes, I would say broadly it would have merit. How we would specify that, I think I couldn't really be precise at the moment. I don't have a clear set of proposals that would achieve that objective.

Mr. WYDEN. Let me ask you one other question on the state of our access to good data in our country. My sense is we don't have very good data, for example, on a number of pharmaceuticals as they are used in children. Do you agree with that?

Mr. LEE. Yes. I think with respect to the elderly there have been some problems because of the limitations on clinical trials, and that has also been true with respect to clinical trials before marketing on children.

Mr. WYDEN. At what point do you think the market really does work in terms of trying to compare pharmaceutical products in relation to each other? My sense is the market does work. It works 4 or 5 years down the road. But what we really need to do is to try to early in a product's life get an assessment of how it works. Do you agree with that?

Mr. LEE. FDA, of course, has the responsibility for safety and effectiveness. The issues around comparative effectiveness, those are decisions that have been made by physicians, and now, of course, through the formulary committees under the plans, there is obviously a great deal of discussion among physicians with pharmacists about comparative effectiveness: Is this drug equal to that drug and should we include it or not include it?

Mr. WYDEN. Do you think the Nation's doctors today have good information on the proper use of pharmaceuticals in children?

Mr. LEE. I would say the information is certainly potentially available, but it is not easily available at the time the physician may be seeing the patient and is prescribing. To make that information more readily available certainly would be an important objective.

Mr. WYDEN. My concern is that your vision is a laudatory one of really being able to compare one product to another, but I think we are dreaming if we think that the government has enough money to do it. I think the question is whether in this legislation we are going to incentivize the private sector to bring this kind of informa-

tion early on in a product's life cycle. I think it's an opportunity, for example, to solve some of the FDA's problems as well with respect to marketing claims by getting the FDA and the companies together early on.

We are anxious to work with you and appreciate the good work that you are doing. We'll have some questions again in a second round.

Mr. LEE. We would be very glad to do that. Thank you.

Mr. WAXMAN. Thank you, Mr. Wyden.

Mr. McMillan.

Mr. McMILLAN. Dr. Lee, I was pleased to hear you comment that the growth of competitive managed care was beginning to exercise some of the discipline that is desirable in response to the gentleman from Oregon's question. I think that's exactly the crucial issue in what we are talking about here. Good, effective managed competition or managed by those who are competing, not by government, probably is the answer. My concern with the proposed plan is that it essentially will mitigate against that kind of competition and force concentration. I just make that comment and hope we can return to that later.

I did have a question I wanted to put to Dr. Smits. Section 2003 of the bill gives the Secretary the authority to exclude from coverage under Medicare a breakthrough drug for which the Secretary has not been able to negotiate an acceptable price. We discussed that. Is there any definition of a breakthrough drug in the bill?

Ms. SMITS. I don't believe there is.

Mr. McMILLAN. Does that simply mean it's new?

Mr. LEE. Although I don't have in my head the definition in the bill, a breakthrough drug would clearly represent a significant therapeutic advance, and it may be a drug for which there is no alternative treatment. In other words, a new treatment for a condition where there is no existing effective treatment available would certainly constitute a breakthrough drug.

Ms. SMITS. Mr. McMillan, I'm sorry, I don't have my copy of the bill with me, but my staff tells me, and I'm quite certain this is right, that the Secretary's authority with respect to negotiating a rebate has to do with all new drugs. In many instances she won't choose to negotiate the rebate; it will simply go into the standard rebate.

Mr. McMILLAN. So it's not strictly breakthrough drug; it's any drug.

Ms. SMITS. It's not just the breakthroughs, no.

Mr. McMILLAN. But I think your testimony goes on to say with reference thereto that the exclusion of a new drug, and I would presume from your statement a drug for which you had not been able to negotiate an effective rebate, would be a rare occurrence.

Ms. SMITS. Yes.

Mr. McMILLAN. If excessive pricing is the problem that we are trying to address, how can you conclude that it would be a rare occurrence? If prices are really out of line here and seniors are suffering from this, it isn't rare, is it?

Ms. SMITS. This particular provision is for the pricing of a new drug. For other drugs, we have a rebate. If the manufacturer agrees to the 17 percent rebate, there is no problem. That percent-

age is based on evidence of the kind of discounts that manufacturers now are traditionally giving to the buyers that they are most aggressively negotiating with.

The circumstances under which the Secretary would choose to exclude a drug would be when there are similar drugs in a similar class at a lower price and this manufacturer refuses to accept a rebate that she believes on the basis of evidence presented to her is a reasonable one.

Mr. McMILLAN. I think this is an example of something that is going to have to be addressed in the bill. In other words, we are asked to assume that the authority granted in the bill will not be unreasonably utilized. Yet this is an enormous concentration of power.

The chairman of the subcommittee has logically directed questions about the adequacy of subsidies under the plan and what happens if the cost of care exceeds the prescribed amount in the subsidy. Then what happens?

We've got information put out by actuaries that indicate that maybe the actuarial assumptions in the health care plan at some \$1,950 per capita may be 30 percent below the real cost of the standards benefits package that is in the plan.

Then we are assured, well, if that happens, the Congress will take care of it. We've got the same thing that applies to the consolidation of responsibility in regional alliances, which are going to have 88 percent of the work force in them right off the bat. Suppose the \$1,950 is not adequate and then the alliances become insolvent. What happens? We were told, well, Congress will have to address that question and take care of it.

I'm not very sanguine about the willingness of Congress to do that. All you have to do is look at the savings and loan debacle, to see what happens when Congress is left to "take care of it."

My line of questioning really has to do with, how can we rely upon something that is not specifically defined simply on the assurance that it's not likely to occur?

Ms. SMITS. Certainly we would be very willing to work with you on the language of pricing of new drugs. The reality is that most new drugs that are substitutable, that are similar to drugs already on the market are priced already with an eye to what the others cost because, for a variety of reasons, people are reasonably cost sensitive about medications. As I say, this is the kind of area where clearly we need debate and discussion about what the best legislative language would be.

Mr. McMILLAN. Would you work towards an end that would put an emphasis, let's say, on health care purchasing groups or alliances to pursue disclosure as opposed to determination by the Secretary as a remedy, disclosure both with respect to price and outcomes research on effectiveness?

Ms. SMITS. We are going back and forth between the plan in general and Medicare. Most Medicare beneficiaries will not be covered through alliances.

Mr. McMILLAN. I'm an advocate of including Medicare in the whole process so that they would be part of those, but I think I'm very much in a minority on that even within my own party.

Thank you very much.



Mr. WAXMAN. Thank you very much, Mr. McMillan.

Mr. KREIDLER.

Mr. KREIDLER. Thank you, Mr. Chairman.

Dr. Lee, all of us are very concerned about de facto rationing. I had a town hall meeting back in my district this last Saturday and heard the story of a lady that had to explain how she was trying to spend something like \$80 a week on prescription medications and she didn't have the money, that she was going to face the decision of either having food to eat or paying her utility bills. That kind of rationing is something that I'm sure that every member of this committee says has to be eliminated. I'm pleased that this is what we are here working on.

I also understand that this bill prohibits price differences to different buyers except on the basis of volume, speed of payment and other specified factors.

Why is the administration becoming involved here with what would be considered normal market processes?

Ms. SMITS. That's in the Medicare segment. Retail pharmacists tell us that even when they band together, even when they offer all of the terms that, say, a hospital does, they are unable to obtain from the manufacturer the same discount that the hospital did.

What we are simply suggesting is that the manufacturer ought to give the same discount provided that the terms and conditions are the same. That is, the pharmacists are going to have to figure out a way to have it all delivered to one place; they may have to make volume guarantees. It would have to be exactly the same kind of agreement. But we feel at this point that because the manufacturers know that the retail pharmacist must eventually buy the drug, those independent pharmacists when linked together have some real difficulty obtaining discounts. That's why this provision is here.

Mr. KREIDLER. Why is there so much controversy over that?

Mr. LEE. I think in relation to, say, the competing health plans, because they not only provide a volume discount, but they also can provide market share, market exclusivity for a single product, so that they can negotiate a different price than can a group of pharmacies, which will have to provide not just a single manufacturer's product, but products perhaps from multiple manufacturers. So although they can get a volume discount, that market share is the thing that would differentiate those two competing approaches.

Mr. KREIDLER. I see.

Dr. Lee, if an advisory committee on breakthrough drug prices is a good idea, why don't we create an advisory committee on the prices of new technology and new medical procedures?

Mr. LEE. On medical devices we do have the FDA approval. For procedures, this is an area where there still is, I think, a lot of work that has to be done with Congress to identify what would be the appropriate policies and how this can best be done.

Within a health plan, of course, if you develop a new procedure and it gets approved and it becomes medically necessary and appropriate, the plans would be deciding, the doctors would be deciding which patients would be given this. There would be limits, of course. You've got capitated plans. So you wouldn't have the kind of situation we have today where a new procedure tends to get



priced at a relatively high level and then over time those prices don't decline. That has been true in this open market that we have today.

I think that probably through the organized systems, through the integrated systems, we would have a much better way to control the expenditures for those. For example, in a fee for service plan you would have negotiated prices at the alliance level.

In the capitated plans that are staff and group model HMO's, even now they have, I think, very good ways of looking at new technology, making decisions about it, and assuring appropriate use through their quality assurance system.

So I think with the plan we have mechanisms that would help to deal with that, but I think that is an area still that we don't have all the answers.

Mr. KREIDLER. FDA only deals with safety and effectiveness.

Mr. LEE. Absolutely.

Mr. KREIDLER. This is a very different criteria.

Mr. LEE. Right.

Mr. KREIDLER. Thank you very much, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Kreidler.

Mr. Upton.

Mr. UPTON. Thank you, Mr. Chairman.

I heard your earlier responses that there were no price controls and that health breakthrough drugs would not be excluded. I didn't know if you were aware of a letter that I'll be glad to furnish you a copy of signed by 565 Ph.D. economists from across the country last month to the President indicating that 'you insist that your health care plan avoids price controls. We respectfully disagree. Your plan sets the fees charged by doctors, hospitals, caps annual spending on health care, limits insurance premiums, and imposes price limitations on new and existing drugs.'

I'll be glad to provide that for you and for the record as well.

I know that you watched the video at the beginning. You saw what happened with Cognex, with Kaiser Permanente. Those things are happening without price controls. Would that type of thing happen under the President's plan?

Mr. LEE. Let me just say, first of all, I don't agree with the economists. I've many times disagreed with economists.

Mr. UPTON. You're supposed to say on one hand this and on the other hand this.

Mr. LEE. That's exactly right.

The basic premise of the President's plan is managed competition among integrated systems based on quality and price—organized delivery systems, information for consumers through the quality report card, a number of mechanisms to stimulate competition. That is not, in my judgment, price control. If that system is not effective, as many of us feel it will be, there is a backup provision for premium control, regulating the premiums that the plans can charge from year to year, the increases in the premiums. In my judgment, that is regulating the rate of increase in expenditures. If the economists choose to call that price control, it isn't regulating the fees charged by individual doctors; it isn't regulating what a managed care plan would pay the physicians. They may be paid on a fee for service basis; they may be paid on a salary basis.

So I think we do have some issues there about definition of what constitutes a price control. I think the basic approach is a competitive approach, not a regulatory approach.

Mr. UPTON. Mr. Chairman, I ask unanimous consent to distribute a chart that I would like to discuss.

Mr. WAXMAN. Without objection, that will be the order.

Mr. UPTON. This chart, Dr. Lee, as you can see, contrasts some of the currently existing dispensing fees for pharmacists with the fee described in the Health Security Act. As you know, the Health Security Act authorizes a \$5 dispensing fee for pharmacists for each prescription written under the Clinton plan and the fees will grow by the CPI each year. As the chart demonstrates, the dispensing fee in the Clinton health care plan is considerably higher than fees which currently exist throughout country. I think that it is particularly striking that this dispensing fee in the Clinton bill is some 300 percent higher than that approved by the FEHB plan because the President's plan always seems to hold that FEHB program as a model program.

My question is with regard to this \$5 fee. What empirical study might it have used? Are these pharmacies selling products through managed care PPO program at much lower dispensing fees? Why should the government, the largest purchaser of drugs, pay more than what pharmacies accept for managed care? Should the government create a committee to study pharmacy dispensing fees? What background do you have for this \$5 fee in regard to some of the evidence you were able to find out?

Ms. SMITS. First of all, these are fees from 2 years ago and we wouldn't expect the drug benefit for Medicare, which is the \$5 fee, to be in place for another 2 years. So there is some allowance for inflation. It is consistent with the kind of fee we are paying under Medicaid.

I would like to remind you that this will require some new work on the pharmacists' part in terms of searching for the drug interactions and providing information to the beneficiary. As you may have noticed, I have made an unfortunate amount of use my health plan since I've been on the Federal employees health benefit program, and I can assure you that the competent local pharmacists didn't do anything but hand the medication to me.

So I think there are a series of reasons why we settled on the \$5. We would be glad to review those with you in detail, though, and if Congress finds reasons, since it is specified in the plan, to change it somewhat, we would be glad to consider that.

Mr. UPTON. I would hope so, because these figures, despite being 2 years, I don't think that it's quite 300 percent.

I yield back the balance of my time.

Mr. WAXMAN. Thank you, Mr. Upton.

Mr. Towns.

Mr. TOWNS. Thank you very much, Mr. Chairman.

Dr. Lee, in treating a patient, say, with hypertension, who should make the decision about which medication the patient receives, the doctor or the government?

Mr. LEE. No question that it should be the physician who is the physician for that patient. That has to be a drug that has been approved by the FDA for safety and effectiveness, but of the approved

drugs on the market the physician should be making that decision. Within a group, within a plan, where physicians have gotten together with pharmacists and developed a formulary, the physicians agree to that formulary, as they do, for example, in the Permanente Medical Group, because they have worked to develop it, and they have determined of those FDA approved drugs, which ones they would prescribe within that group for their patients.

So there are some limits. As Dr. Smits noted, in her hospital there was a formulary. Again, that's a formulary decided by the physicians within that particular institution.

Mr. TOWNS. Let me just say that I am looking at your testimony and it talked in terms of everybody that you consulted with. I think that sort of sounds good, but I think it would be important to know in terms of what some of them said. I'm having great difficulty finding folks that agree with this concept. I notice you indicated in your testimony that you talked to advocates for children; you talked to Members of Congress; you talked to the biotechnology people; you talked to manufacturers. You talked to everybody, according to this. I think that is nice to say, but I think it's more important in terms of what did they say. I think that would be important to sort of get a feel for. As I move around the country and even in the hearings that we are getting here that people are very concerned and there seems to be not a lot of support across the board.

Mr. LEE. Not a lot of support for which provisions? I think we see broad support for coverage of everyone. We see, I think, at least in the conversations I've had with many people, the approach that we have taken in terms of managed competition has a lot of support. There are some individuals who don't support that approach. But within a plan, what we are proposing is what is widely practiced already within managed care plans, namely, the use of a formulary developed within the group by the physicians and the pharmacists in the group.

There are some people who advocate no limits, that physicians can prescribe any drug. One of the serious problems we have today is, although we have very good drugs on the market, when they are not used appropriately, that is a problem.

Mr. TOWNS. Let me give you another example. What I am hearing from patients out there, they are saying, don't we have a say in this process? Can't we make a suggestion? Can't we make a recommendation in terms of certain types of medication? I'm getting this especially in the black community when it comes to hypertension in terms of what should be prescribed. We are hearing this a lot. I'm saying what about the patient having some input in this process as well.

Mr. LEE. I think there are two things. First of all, I would agree it's very important for the patient to be involved in those decisions and for the patients to be given the information about the drugs so that they can, with their physician, make a choice if there are alternatives available.

Second, within the plan that we are proposing, if in a plan, for example, either a physician or a patient wants to receive a drug that isn't included in the formulary, there is an appeals process that is spelled out, much more than I think exists in many man-



aged care plans today. There has to be an appeals process. There has to be a review using an external provider, for example. Both the regional and corporate alliances would have to establish these review processes, and there would be an ombudsman associated at the alliance level. So there are advocates for the patient, and the quality report card would also give patients broad information about their plans, and the patients' opinions about those plans would be included in these quality report cards.

We think that there does need to be more information made available to patients in language that is easily understood so that not only when the medicine is prescribed that there is agreement with the patient about that, but also so the patient can take the medication as it has been prescribed. In other words, what we call compliance can be improved, because many patients now do not take the drugs as prescribed.

Mr. TOWNS. My time has expired. Let me just jump to something else very quickly, the research and development part. I'm hearing from physicians. I'm hearing from everyone. They are concerned about the fact that what we are doing here would limit research and development. That is something that I must admit that I am very concerned about. Aren't you hearing this too?

Mr. LEE. Yes. We have talked with a number of manufacturers, and I think that the concerns that have been expressed relate particularly to the breakthrough drug provisions. We've heard that from biotech and also from the large pharmaceutical companies, and I'm sure you will be hearing that further today in testimony.

I would say that as we have looked at this, and we are continuing those discussions as to what is the best mechanism for that, with everybody covered for all prescription drugs, there is a concern about the prices for those drugs. We just have to find a mechanism that assures affordability. This is an area that I think has been one where a lot of concern has been expressed to us about it.

Mr. WAXMAN. Thank you, Mr. Towns.

Mr. Greenwood.

Mr. GREENWOOD. Thank you, Mr. Chairman.

Dr. Lee, talking specifically about the breakthrough drug issue, I have some concerns about whether price controls and global budgeting could have a devastating impact on the introduction of new breakthrough pharmaceuticals and other life saving medical technologies. I would like to direct your attention to the chart. I believe you are being delivered two charts. The one I will be referring to first is the chart with the red circle with the hatch through it on the bottom right.

Simply put, this is the dilemma. How can new breakthrough drugs and other new technologies be paid for in a health care system that is under a zero growth global budget? Would we end up squeezing out the waste and the fraud and the duplication that we aim to, or will we in fact squeeze out innovation and invention?

With regard to new breakthrough drugs, the administration will give physicians a Hobson's choice. The unpalatable choices both depend on rationing medical services or drugs. One, either these new breakthrough drugs will be rationed to the American public, or two, physician and hospital services will have to be rationed to provide the public these new drugs.



Dr. Lee, these two charts describe these two choices. When I am finished, what I would like you to do, if you would, as the administration's top physician, is to make the choice that you would make if you were the doctor in question.

The first chart describes a scenario where the American public is denied access to new breakthrough drugs. In the chart we are simply starting with the \$2,000 individual premium and allocating the premium to typical cost centers or categories of health care, 65 percent, or \$1,300, allocated for physician medical services, 30 percent, or \$600, for hospital services, and 5 percent, or about \$100, for the pharmacy. These percentages represent typical HMO capitation rates.

As we know, the administration's bill in the year 1999 keeps all premiums constant in real terms because of the CPI premium cap. Therefore the premium in 1999 adjusted for inflation will still be \$2,000 in real terms. However, in 1999, let's assume that the pharmaceutical industry introduces the following breakthrough drugs: An AIDS drug, a new diabetes drug, and a new arthritis drug.

After an exhaustive examination of company books, the new Advisory Council on Breakthrough Drugs finds that the launch price for each of these drugs should be about \$2,000 per patient for a year's treatment.

Now the health care plan has a big problem. If it makes all of these new breakthrough drugs available, the plan will dramatically overshoot the alliance premium cap. Remember, if the plan is over the alliance premium cap, under the provisions of H.R. 3600, it is in violation of Federal law. To remain under the premium cap and remain in compliance with the law, the health care plan refuses to place these three drugs on its formulary, denying access to patients who could benefit from these drugs.

Now let's look at the second scenario and the other of the chart that I circulated to you in which physician and hospital services will be cut to pay for these new breakthrough drugs under a CPI premium cap. Let's look at the year 1999 in the second chart. This plan decides to prescribe these new breakthrough drugs to all patients in the plan who need them. However, its pharmacy budget jumps to \$160, or now 8 percent of the premium rate per individual. Let's emphasize that this increased spending is due solely to the introduction of new breakthrough drugs and not price increases in existing drugs.

Because the plan must remain under the alliance premium cap or be out of compliance with Federal law, funds must be shifted from the physician and the hospital cost pools to make up the difference. In this example physicians and hospitals have experienced real expenditure declines and medical and hospital services have been cut. Physicians now clearly realize that every time they prescribe one of the new breakthrough drugs they are cutting funds for other medical treatments.

In these two scenarios physicians are facing this Hobson's choice. With a global budget which is limiting real growth in health care expenditures to zero, they are either going to ration medical care or access to breakthrough pharmaceuticals.

Dr. Lee, this is precisely the dilemma that the Physician Payment Review Commission, which I believe you chaired, identified

in a July 1993 report entitled "Expenditure Limits, Design and Implementation Issues." Chapter 4 of this report is entitled "Allocation of Expenditure Limits to Categories of Services" and discusses this issue.

Dr. Lee, as the Federal Government's top physician, which choice would you make, ration access to new life saving drugs or ration medical or hospital care?

Mr. LEE. Let me say, I don't believe that would be the consequence, Mr. Greenwood. First of all, of course, without coverage of prescription drugs today, we are rationing care on the basis of price. Many people can't afford the drugs.

If we did indeed have these breakthrough drugs developed, one would assume that there would be significant savings either in reduced hospitalization or reduced needs for other services. As we have seen, for example, when we developed penicillin, patients did not have to be hospitalized. They were cured in very short order from many conditions.

Mr. GREENWOOD. I have used my time. The concern is that the savings would not likely be seen in the same year in which the premium cap applies.

Mr. LEE. We can give you a more detailed response, if you wish, for the record on this issue. It is a complicated question. I would be glad to sort of personally develop a response and provide that to you for the record, if that is OK.

Mr. GREENWOOD. I would appreciate that very much.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Greenwood.

[The response from Dr. Lee follows:]

Breakthrough drugs can offer many benefits to a quality and cost-conscious health care system. The patient's overall health status and often lifespan can be improved, bringing benefits that extend beyond the monetary calculations. Yet frequently there are also savings in health care expenditures stemming from use of the drug. These savings may include both short- and long-term savings.

The case of ulcer treatment is probably an excellent example of how short- and long-term savings often interact with one another.

Until the 1970's, serious stomach ulcers often required surgery that now costs \$25,000 or more. Introduction of H2-blocker drugs in the 1980's allowed for effective nonsurgical treatment with drugs now costing under \$1,000 per year. Recently, further research has pointed out the potential to replace this long-term symptomatic treatment with short-term drug therapy that actually destroys the bacterium that contributes to ulcer development. An NIH consensus conference in February endorsed a short-term antibiotic regimen costing under \$100.

This means that what was once a \$25,000 surgery with long-term follow-up costs could soon become a \$100 course of treatment with less need for costly physician follow-up. This is a clear example of new drug therapies leading to lower medical costs in both the short- and long-run. Most breakthrough treatments seem to follow this pattern, reducing both short- and long-term costs.

In some cases, of course, the equation is not so simple. Short-term costs may actually go up if the drug is more expensive than the less effective therapies it replaces. These short-term costs are typically, but not always, overtaken by long-term savings as better patient outcomes materialize. The so-called "clot-busting" drugs such as TPA for use after heart attacks appear to fall into this category, according to recent clinical trials.

In other cases, short-term costs can drop while long-term health costs increase. This could occur if the drug provides significantly longer lives, which means medical care for a longer period than patients formerly enjoyed. Experimental gene therapies for severe immune disorders may begin to fall into this category, as patients begin living years longer than under current therapies and accordingly incur health care costs for more years than is currently possible.

The interaction of short- and long-term costs is further complicated by the fact that while costs are typically viewed in terms of health care costs, the benefits extend far beyond the health insurance system. For this reason, most evaluations of a new therapy do not stop with mere cost comparisons alone but look at indicators such as cost-efficacy, cost-effectiveness, and quality of life as well.

The new breakthrough drug advisory board that is established under the Health Security Act to provide information to public and private purchasers is a case in point. In reviewing the cost of a particular new medication, this board is explicitly directed to evaluate not only the costs of producing the new drug, but the drug's cost effectiveness relative to other medical interventions. In addition to the Act's provision that directs the advisory board to review costs relative to the potential to help patients return to work, comparing drug prices to alternative treatments makes sense and was something the drug manufacturing industry strongly supported.

Because most new drugs appear to offer short-term savings over existing therapeutic alternatives, it seems unlikely that including outpatient prescription drug benefits with a standard benefits package will impose excessive short-term costs to the health care system. Yet in any case, the increase in health status that frequently cost-effective drug therapies can represent makes it imperative that cost-effective pharmaceutical treatments be included under health care reform.

Mr. WAXMAN. Mr. Paxon.

Mr. PAXON. Thank you, Mr. Chairman.

I'm going to go back, if I could, for just a moment. I just want to make a point and then go on to some questions.

Mr. McMillan followed a line of questioning regarding exclusion under Medicare. I just want to reiterate a concern that we have, and I hope you can help us with this during your testimony today and in the future.

Section 2003 of the bill gives the Secretary the authority to exclude from coverage under Medicare a breakthrough drug for which the Secretary has not been able to negotiate an acceptable price. Your testimony acknowledges this but then goes on to state, "The exclusion of a new drug from the Medicare program is expected to be a rare occurrence."

You just said to Mr. Greenwood, Dr. Lee, that, in regard to his issue, one would assume, and went on to make your case: expected to be a rare occurrence; one would assume. Then we have had two dozen hearings on this legislation, on the health care plan, and we have been told things like "it will not be a problem in regard to what will happen to subsidies for the poor or small business once the spending caps are reached," Mr. Waxman's question recently. And it goes on and on. We keep being told "one would assume," "one would deduce."

I want to go back and say, in regard to Mr. McMillan's question, you didn't really address it, and I would hope that at some point you can come back and show the subcommittee the specific provisions in H.R. 3600 that guarantee the elderly access to tomorrow's breakthrough drugs, specific provisions in the legislation. I know you said, Dr. Smits, you didn't have it with you and you'd get back to us, but I would hope that you could develop for us the specific provisions. You can see some of our concern here with not being very specific.

Dr. Lee, according to the Bureau of Labor Statistics drug price inflation for 1993 has moderated to 3.1 percent. This appears to be a reasonable indication that the competitive marketplace is working to constrain drug costs. Doctor, why would we want to move toward government control of drug prices if the marketplace is containing price increases this effectively?



Mr. LEE. As I indicated in my testimony and in the response to several questions, we are proposing that the approach be managed competition, not price controls. That is the whole thrust of the President's plan, and the mechanisms used by managed care plans such as formularies, use of generics, and other approaches are currently able to produce very significant discounts for organizations like Kaiser Permanente, Group Health of Puget Sound, Harvard Community Health Plan, and other managed care plans. That certainly is having a moderating effect, and that is really the basis for the approach in the President's plan for those under 65.

Mr. PAXON. Doctor, what percentage of the current market do generic drugs occupy, approximately?

Mr. LEE. I don't have that figure in my head but we could certainly provide it for you.

Mr. PAXON. About 30 percent is my understanding.

Mr. LEE. It has grown quite rapidly in the last 5 years and we anticipate it will continue to grow over the next 5 years.

Mr. PAXON. To what level will it be at the end of the century? Do you know?

Mr. LEE. I don't know that but we could certainly give you that figure. My guess is it will be over 40 percent.

Mr. PAXON. It will be closer to 50 percent by the end of the century.

Doctor, wouldn't it seem to indicate that if the generic market is growing from 30 to 50 percent with its ability to help bring down overall prices that the marketplace is working without this massive new government control that you are advocating in your legislation?

Mr. LEE. Again, we are not advocating government control but rather competition, and the generics would be a significant part of that. There are other elements that would contribute to achieving the kind of moderation in price increases that we seem to be achieving in 1993.

Ms. SMITS. It is also important to note that under Medicare manufacturers will not pay rebates on their generic drugs. That recognizes the market forces.

Mr. PAXON. I just want to make a concluding thought and I won't ask any more questions today. We had a hearing the other day, Dr. Lee. You testified regarding legislation as it applies to medical education.

This past week I have been talking with a number of medical educators in my district who are very concerned not only with the legislation but, quite frankly, with some of the responses we received that day.

But it underscores a real concern I have as a representative after 6 years of every day trying to battle government agencies to get answers in many cases on issues that don't affect the life and health of our constituents. We were talking about the ability in those hearings of this government to direct the medical education of every student in this country and it will affect every citizen of this country and their health care need.

Today we are talking about the ability of this government under this plan to direct the pharmaceutical industry and its effect not



only on health care but the economy and on the job market in this country.

Doctor, I don't direct this point to you; I direct this more generally to the administration's plan. When I see this and I hear this testimony on the Hill and then every week, as I do, return to my district, the public raises questions, and I think it revolves around one word. It's something the administration should look up. It's called hubris. I'm not certain we have the ability in this government to make these kind of decisions and controls over this much of our economy when we are getting answers that continue to talk about "it is expected to be" or "one would assume" as the answers to these issues.

Thank you.

Mr. WAXMAN. Thank you, Mr. Paxon.

Mr. Brown.

Mr. BROWN. First, a comment about Mr. Paxon's statements about the marketplace seeming to work so well. I brought up and a couple other members brought up a Wall Street Journal graph of 1 or 2 weeks ago showing how when Richard Nixon talked about his health care proposals that pharmaceutical prices and prices throughout the health care industry, the increases abated or sometimes plateaued or sometimes slightly decreased in some industries. That year, after the Congress disposed of it the way they too often do on health care issues, prices more than made up for that plateauing of price increases the next year. The same thing happened when President Carter talked about it. The same thing could be happening now.

I think we should all caution ourselves and quit patting ourselves on the back saying, boy, the fact that we are talking about health care reform in this Congress means that all kind of good things are happening; we can sit back as good things will continue to happen. Maybe they will, maybe they won't, but I don't think we can just say it's wonderful, the marketplace is working.

Sort of on the flip side of that a bit, Dr. Lee, I want to follow up on what Mr. Towns said. I go home and constituents say to me drug companies are charging too much, you got to do something about the drug companies, they are charging less in Europe than they charge us, this price increase has gone up this much. All of the kinds of things that voters are saying, that customers of pharmaceutical companies are saying.

The other side of that is we hear again and again the proposals established by the President are going to limit research, that there will be fewer breakthroughs, that if we do anything, it is ultimately going to cause long-term price increases instead of wider availability of pharmaceuticals, that we'll lose the opportunity to replace invasive procedures with pharmaceutical alternatives, all of those things that the drug companies are arguing.

You didn't do it with Mr. Towns' question. You need to assure us with the Clinton health plan, with the proposals to rein in pharmaceutical costs that we will not lose the biotechnical research advantages that this country can be proud of in the last many, many years. We just haven't been assured. You need to do that, if you would, doctor.

Mr. LEE. Let me just very briefly say, one, with the larger market, with increased revenues for the firms, and those particularly that develop new products that represent significant therapeutic advances, there is an incentive for them to do that in this managed market where everybody is covered.

Second, and I think the President's budget yesterday reflects this, not only in increased funding for NIH in that budget, despite the constraints that we have on the Federal budget, but also in the Health Security Act, where there are additional provisions for expanded research in NIH. So there is a very significant commitment on the part of the administration to research both through the support of NIH funded research, through these market mechanisms to assure the continued viability and thriving of this very, very productive industry, to assure that patients get the drugs that they need and that physicians can prescribe those drugs as they see fit. We believe the plan really does that and does it in a very appropriate way.

Mr. BROWN. Dr. Smits, one question for you. You mention in your statement with not much detail a Rand study which demonstrated that more than 40 percent of prescriptions for those over 65 are inappropriate. Tell us more about it. Elaborate on the mechanisms included in the President's plan to ensure Medicare beneficiaries access to appropriate and appropriately priced medicines.

Ms. SMITS. The Rand study takes a very rigorous view of "appropriate" in terms of looking at drugs where something else could have been used, being very careful about drug-drug interactions. As I am sure you know, there is a lot of concern about use of drugs such as tranquilizers in the elderly.

The President's proposal would not try to impose something that rigorous on every physician. What it would do is provide that the pharmacist must educate patients about the medications that they are taking. It would eliminate duplications and conflicting drugs through the use of an automated system, as I have described. It would provide for retrospective review of prescribing habits so that inappropriate patterns among certain physicians or in certain areas could be identified, and there would then be ways to work with people to try to correct that.

I understand the time is up. We would be glad to provide a full explanation for the record.

Mr. BROWN. One more question.

Mr. WAXMAN. Yes.

Mr. BROWN. Thank you, Mr. Chairman.

Dr. Smits, is it fair that the President's plan uses price controls to control drug prices for Medicare beneficiaries while relying on the competitive marketplace that Dr. Lee talked about to deal with drug prices for under 65 population? What is the public policy rationale for that?

Ms. SMITS. The President's approach uses a variety of means to control drug prices under Medicare. They are not simple price controls. In particular, it asks for discounts based on discounts given to very large buyers. Not the best discount you give, but the weighted average discount you give, which we think is fair.

I don't think a straightforward Federal decision about how much each drug price should increase each year is the logical way to go.

We think this is a very good mix of incentives and required discounting to the Federal Government that will benefit the drug manufacturers and the pharmacists as well as the patients.

I would like to note that the Medicare benefit is estimated, even after rebates, to put an additional \$24 billion plus of revenues into drug companies in the first 5 years. That's just Medicare, not the rest of the benefit. It's hard for me to believe that some of that can't in turn be used for more research and development.

Mr. LEE. Let me make just one additional comment, if I might, Mr. Chairman, on this question to answer it a little bit more specifically about Helen's comment about the additional billions of revenues. For the brand name manufacturers, those additions would be about \$16 billion of that total just for Medicare, which means additional funds available for research and development. That does not count the additional revenues that would come from coverage of everyone under 65. So there is a major stream of funds available for research and development as a result of the plan.

Mr. BROWN. Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Brown.

I understand that Mr. Bliley wanted to ask some additional questions and he has designated Mr. Greenwood to pursue a second round on behalf of the Republican side. I have no further questions here, but Mr. Wyden wanted another opportunity to ask some questions. So we will recognize him and then after that we will take a short break.

Mr. Greenwood.

Mr. GREENWOOD. Thank you, Mr. Chairman.

Just one question. I would like to direct this to you, Dr. Smits. I would like to reference section 2003(c)(3)(B). This section places the entire pricing structure of the U.S. pharmaceutical industry at the mercy of currency exchange markets and speculators. The provisions of this section state that in the case of drugs marketed in 21 western countries, the Medicare rebate may equal the difference between the average manufacturer's retail price in the United States and the price available to wholesalers in those countries.

Let's examine the chart to see how actual exchange rate variations would affect the U.S. Medicare rebate. In this example, based on actual data, a drug is introduced in the United States, Italy and Sweden at the equivalent of \$1 per unit. This means that at the drug's launch the price is exactly the same in these three countries.

Now look at how the price differs in these three countries 1 year later. Of course, the U.S. reference price will remain constant at \$1. However, strictly because of exchange rate variations in their currencies, the drug's price in Italy is the equivalent of 83 cents and the price in Sweden is 72 cents.

By taking this 1-year snapshot of exchange rates, we can see that in September 1993 the Secretary could demand a rebate of almost 30 percent. In fact, because the Medicare rebates are calculated on a quarterly basis, the Medicare rebate would always be a moving target.

Now let's look at this next chart. In this chart, during the last quarter of 1993 Italy experiences a dramatic currency devaluation. The drug's price in Italy is now the equivalent of 60 cents. There-



fore, in this last quarter, under this provision the Secretary could demand a 40 percent rebate.

Of course, these exchange variations would be endless. They would have to be monitored in 21 different countries simultaneously, and during every quarter the Medicare rebate would be set by the lowest price in these 21 countries. For new breakthrough drugs, U.S. pharmaceutical prices would be at the mercy of currency speculators.

In this environment, I find it impossible to believe that any company would commit the hundreds of millions of dollars needed to bring a new drug to market.

Dr. Smits, can you or anyone else in this administration tell us how these provisions would really work in the real world?

Ms. SMITS. First of all, the provisions which consider international prices are applicable only to the negotiated rebate on new drugs, which is negotiated once and then is done. You don't get to renegotiate it in another quarter or another 6 months. Once it is accepted, it's in the system.

I certainly share your concern about inequities that could result from exchange rate changes. Certainly we would be willing to look at things such as provisions that would look at exchange rates retrospectively over time so that rapid recent changes don't unfairly affect this.

The fact is that this is a relatively small part of the rebate program. This is only those situations where the Secretary chooses to negotiate beyond the 17 percent with the manufacturer.

Mr. GREENWOOD. I recognize that it can be construed as a relatively small part of the process, but the part that it affects is the breakthrough drugs.

Ms. SMITS. It affects all new drugs, not just breakthroughs.

Mr. GREENWOOD. It certainly affects the breakthrough drugs, and the concern that I am trying to express here is this: say you are an investment banker or you are a pharmaceutical company and you are considering investing hundreds of millions of dollars in research into a product. You know that the price that you can receive for it on the market following the rebate is going to be affected by such uncontrollable items as foreign currency devaluations. Aren't you going to be concerned that investment capital will flow to other places, rather than into the innovation of new pharmaceutical products?

Ms. SMITS. Many of our drug manufacturers are multinationals with manufacturing plants abroad and considerable experience at handling the intricacies of exchange rate changes. So I don't think a priori it would necessarily eliminate investment. But again, we would be very happy to work with you in ways that would make this provision fair and reasonable to the drug companies.

Mr. LEE. That is really only one of the considerations that the Advisory Council would look at. Clearly, if that kind of problem developed, that would be considered. In other words, it would not just de facto take those prices as the given. I think this kind of information certainly would be considered, as would the prices of other drugs in the same therapeutic class or a number of other things. This would not be the sole source of judgment with respect to that council certainly.



Mr. WAXMAN. Thank you, Mr. Greenwood.

Mr. Wyden.

Mr. WYDEN. One question, Mr. Chairman.

Dr. Lee, I was puzzled by your responses to my question, because they seem to contradict what is in your printed testimony.

For example, on page 4 you say, "We need to know much more about which drugs, biologics, and medical devices work best for which patients, under what conditions, and at what cost." At page 5 you say, "This need is particularly acute in the period when a new drug or device first enters the market."

The breakthrough council is going to be doing evaluations of cost-effectiveness relative to the cost of alternative course of treatment options and improvements in quality of life offered by the new product.

My question is, how is the severe lack of early objective comparative data consistent with the charge of the breakthrough council to rely precisely on this kind of information?

Mr. LEE. As I said in my response to your question, we do need to develop more information. We do need to be working with you to see what kind of incentives, as you have proposed, might be included and to find ways to develop this information. Obviously the manufacturers are producing some of that information now. As a matter of fact, in some areas they are well ahead of what we are doing in the government.

We need to get that information. We need to be looking at that with NIH with respect to clinical trials, for example. We need to be doing that in the Agency for Health Care Policy and Research where we are doing it more explicitly. Clearly the manufacturers need to be developing that information, because clearly it will be important. How we do that, how we create the incentives to do that, I think is a question that we have to work together to resolve.

Mr. WYDEN. That sounds more reasonable.

Mr. Chairman, I want the record to reflect that Dr. Lee is interested in the question of incentives to get the private sector to do this research. The fact of the matter is it's not getting done. The government doesn't have enough money to do it.

I appreciate your clarifying that for the record.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Wyden.

Dr. Lee, Dr. Smits, we thank you for being here. Obviously as we look at this problem we want to provide drugs to people under Medicare and those who are going to be in this new national health insurance program. This is a fundamental medical benefit. You provide in this legislation the payment of pretty much whatever the manufacturers charge. We can't afford that. We've got to figure out some way to balance out the need for prescription drug coverage with reasonable cost containment. That, I think, is the task before us, and we thank you for your presentation.

Ms. SMITS. Thank you, Mr. Chairman.

Mr. LEE. Thank you very much, Mr. Chairman.

Mr. WAXMAN. As I mentioned earlier, we have a very long schedule of witnesses. Because of that, we are going to break only for a half hour so that members can grab a sandwich. Unfortunately,

if those of you here in the audience want to grab a quick bite, you'll only have a short time as well.

We will reconvene in this room at 1 o'clock.

[Whereupon at 12:30 p.m. the hearing was recessed, to reconvene at 1 p.m. this same day.]

[The following letter was submitted for the record:]

DEPARTMENT OF HEALTH & HUMAN SERVICES,

March 17, 1994

Hon. HENRY A. WAXMAN,

*Chairman, Subcommittee on Health and the Environment,*  
*Washington, D.C.*

DEAR MR. WAXMAN: Thank you for the opportunity to clarify remarks I made at the subcommittee's February 8 hearing on prescription drugs.

Following the recent Robert Novak column ("Health Care Hawks," Washington Post, February 24), I would like to clarify my use of the term "price control." You had asked why the rebate called for in the President's plan goes to the Federal Government instead of the consumer in the form of a price reduction (see page 41 ff of the enclosed transcript). I replied that there are "price controls" in addition to the rebate to ensure that pharmacists charge individuals a reasonable price. By this I meant that the Health Security Act proposes other means to contain costs for consumers, including the use of lower cost generic drugs, when appropriate, and the requirement that pharmacists accept assignment and charge no more than Medicare will pay. Perhaps I should have more accurately used the term "cost containment provisions" rather than "price controls."

Ultimately, rebates provided to the Federal Government should contain the overall cost of the Medicare prescription drug benefit, which will be passed on to beneficiaries in the form of lower prescription drug premiums. Also, beneficiaries would benefit from lower retail drug prices since the rebate provisions encourage manufacturers to maintain price increases at or below inflation.

Let me also refer you to my response later in the hearing to a question from Mr. Brown regarding Medicare price controls for prescription drugs (see page 80 ff of the transcript). Here, I clearly point out that the President's plan does not contain price controls, but instead includes a variety of approaches to control drug prices under Medicare.

I regret that my responses at the hearing have been mischaracterized to reflect something other than the Medicare prescription drug benefit proposed in the Health Security Act. I would be pleased to discuss this with you further if you so desire.

Sincerely,

HELEN L. SMITS, M.D., *Deputy Administrator*

#### AFTER RECESS

Mr. WAXMAN. The subcommittee will come back to order.

The witnesses on our second panel are Patricia Johnson, President of the Lupus Foundation, Abbey Meyers, President of the National Organization for Rare Disorders, Joseph Perkins, member of the Board of Directors of the American Association of Retired Persons, Daniel Perry, Executive Director of the Alliance for Aging Research, and Dr. Sumner Yaffe, Director of the Center for Research for Mothers and Children, National Institute of Child Health and Human Development at National Institutes of Health.

We are pleased to welcome you to our hearing today. Those of you who have prepared statements, we will have those prepared statements in the record in full. We would like to ask, however, that you limit the oral presentation to no more than 5 minutes. We'll have to be fairly strict. So when you hear the bell, if you would just make a concluding sentence. We'll have to move on. That will be the only way we can get through all the witnesses and have a full opportunity for questions and answers, as arbitrary as that may seem.

Let's start with Ms. Johnson.

**STATEMENTS OF PATRICIA A. JOHNSON, PRESIDENT, LUPUS FOUNDATION OF AMERICA; ABBEY S. MEYERS, PRESIDENT, NATIONAL ORGANIZATION FOR RARE DISORDERS; JOSEPH PERKINS, MEMBER, BOARD OF DIRECTORS, AMERICAN ASSOCIATION OF RETIRED PERSONS; DANIEL PERRY, EXECUTIVE DIRECTOR, ALLIANCE FOR AGING RESEARCH; AND SUMNER J. YAFFE, DIRECTOR, CENTER FOR RESEARCH FOR MOTHERS AND CHILDREN, NATIONAL INSTITUTES OF HEALTH**

Ms. JOHNSON. Mr. Chairman and members of the subcommittee, I am Pat Johnson. I am President of the Lupus Foundation of America and Director of the Lupus Foundation of New Jersey. My testimony today is on behalf of the national foundation.

We thank you for this opportunity to appear before you to express our views about the possible dangers of President Clinton's health care reform proposal, particularly as it could affect medical research. I would like to specifically address the key issue of access to proper medications and to insurance. I am speaking today for the concerns of millions of people who could be dramatically affected by this plan.

It appears that the Clinton health care plan focuses heavily on preventive health care and cost containment. Our biggest fear is that this legislation does not address the needs of the more than 100 million chronically ill people in this Nation who require continuing access to quality medical care and vital medications.

I know, Mr. Chairman, that you have long been a champion in the fight to bring medical services to those in need. We want to express our deep and sincere thanks for your efforts.

You have also been critical of the pricing practices of the drug industry. Let me approach this issue from the perspective of patients with chronic illnesses or diseases without a cure.

Let me start by telling you a little about lupus, a disease that afflicts as many as 500,000 Americans and an estimated half million yet undiagnosed. Family members and loved ones are also touched by the disease, both financially and emotionally.

Lupus is a chronic inflammatory disease of the connective tissue caused by an overactive immune system which can affect any vital organ or part of the body.

There is no cure for lupus. People with lupus must live with the pain, fatigue and medication side effects for their lifetime.

It's a disease with an unpredictable prognosis and difficult symptoms, among which are extreme fatigue, ongoing, low-grade fevers and debilitating joint pain. This disease can cripple and kill people in the prime of their lives.

It is intermittent, recurrent and difficult to cope with. Therefore, it often causes family problems. It is a lifelong battle for those who have it and for their families.

For unknown reasons, more than 85 percent of lupus patients are women in the childbearing years, but men, children and older people also have lupus.

Lupus is one of 67 severe and often debilitating chronic autoimmune disorders which together affect an estimated 8 million Americans. These diseases include multiple sclerosis, rheumatoid arthritis and Addison's disease.



Many lupus patients also suffer from other autoimmune conditions. Most people with autoimmune diseases share one thing in common: their disease is controlled only by daily medications. It is important to keep in mind that a research breakthrough for any of the above conditions might also be beneficial for those with lupus.

In the past, I have heard arguments that too much money has been spent on research for so-called 'me-too' drugs. Let me make it very clear. There is no such thing as a me-too drug for patients because there is no such thing as a me-too patient. The truth is that a drug that works for one patient may not work for another even if the same condition is shared. Giving lupus patients the wrong drug can cause them great physical distress or even kill them.

Let me point out a few other critical and related concerns. Appropriate medication is often determined only through trial and error. Patients frequently require combinations of medicines to bring their symptoms under control. Patients also are apt to be extremely allergic. Therefore, they can only tolerate one or two specific drugs in a given therapeutic class, and since they must take so many other medications—from 9 to 20 pills a day is not unusual—they must be concerned with drug interactions and dangerous side effects. Because the immune system is compromised, drug side effects can be devastating and costly. Long-term use of some steroids, for example, can cause a softening of bones and require patients to undergo costly hip and knee replacements.

What lupus patients desperately need are more medicines, more choices, and more options that can help them cope with their painful affliction. The one hope they have is that advanced medical research may bring a cure.

What concerns me most about the President's proposals for drug pricing is that I fear they will curtail the options available to people with lupus.

My first concern is that without continued and increased research and development, there may never be a cure. It would be tragic to create a new health care system that discourages cost-saving medical research and denies patients new therapies and cures.

The most likely source of any future lupus cure is the biotech industry, either by itself or in partnership with an established pharmaceutical firm. News that a small biotech company in California plans to start human clinical trials on a vaccine therapy for lupus was most heartening.

However, I fear that price restrictions, either direct or indirect, could stop that research dead in its tracks. Biotech venture capital has already dried up with the talk of price controls. Clinical trials are also being postponed.

Nor will price controls achieve long-term savings for the health care system. Improper treatment of lupus patients can result in costly hospitalization, which certainly is more expensive than if they had received proper treatment in the first place.

We are also concerned about provisions that would limit access to the full range of medicines by forcing patients to only use generic drugs. Let me reiterate. All patients do not react the same way to the same drug. The only way to protect lupus patients adequately is to provide access to all available medical therapies.



With this in mind, let me also note our concern with recent suggestions by the Food and Drug Administration to limit so-called 'off-label' uses of medications. Such an action could jeopardize the health of hundreds of thousands of lupus patients.

Currently there is only one medication specifically approved for lupus—prednisone. For some patients this medicine produces the terrible side effect of crippling osteoporosis. Fortunately, certain other anti-inflammatory, antimalarial and chemotherapy drugs have been prescribed with some success for lupus patients. Restricting their use would be a giant step backwards.

Mr. WAXMAN. Thank you very much, Ms. Johnson. That whole statement is going to be in the record.

Ms. JOHNSON. Certainly, sir.

[The prepared statement of Ms. Johnson follows:]



Foundation of America, Inc.

PATRICIA A. JOHNSON  
PRESIDENT  
LUPUS FOUNDATION OF AMERICA, INC.  
BEFORE THE  
SUBCOMMITTEE ON HEALTH AND ENVIRONMENT  
COMMITTEE ON ENERGY AND COMMERCE

UNITED STATES HOUSE OF REPRESENTATIVES

FEBRUARY 8, 1994

Mr. Chairman, and Honorable Members of the Subcommittee:

I am Patricia Johnson, President of the Lupus Foundation of America and Executive Director of the Lupus Foundation of New Jersey. My testimony today is on behalf of the national foundation.

Thank you for this opportunity to appear before you to express our views about the possible dangers of President Clinton's health-care reform proposal, particularly as it could affect medical research. I will specifically address the key issue of access -- to proper medications and to insurance. I am speaking today for the concerns of millions of people who could be dramatically affected by this plan.

It appears that the Clinton health-care plan focuses heavily on preventive health care and cost containment. Our biggest fear is that this legislation does not address the needs of the more than 100 million chronically ill people in this nation who require continuing access to quality medical care and vital medications.

I know, Mr. Chairman, that you have long been a champion in the fight to bring medical services to those in need. We want to express our deep and very sincere thanks for your efforts.

You have also been very critical of the pricing practices of the drug industry. Let me approach this issue from the perspective of patients with chronic illnesses or diseases without a cure.

I believe you that you may have been misinformed about the potential impacts of the Clinton health-care plan on those with chronic illnesses.

Let me start by telling you a little about lupus, a disease that afflicts as many as 500,000 Americans and an estimated half-million yet undiagnosed. Family members and loved ones are also touched by this devastating disease both financially and emotionally.

Lupus is a chronic inflammatory disease of the connective tissue caused by an overactive immune system. It can affect any vital organ or part of the body.

There is no cure for lupus. People with lupus must live with the pain, fatigue and medication side effects for their lifetime.

Lupus is a disease with an unpredictable prognosis and difficult symptoms. Among those symptoms are extreme fatigue, low-grade fevers and debilitating joint pain. This disease can cripple and kill people in the prime of their lives!

Lupus is intermittent, recurrent and difficult to cope with. Therefore, it often causes family problems. It is a lifelong battle -- for those who have it and for their families and loved ones.

For unknown reasons, more than 85 percent of lupus patients are women in the child-bearing years, but men, children and older people also have lupus.

Lupus is one of 67 severe and often debilitating chronic autoimmune disorders, which together affect an estimated eight million Americans. These diseases include multiple sclerosis, rheumatoid arthritis and Addison's disease.

Many lupus patients also suffer from other autoimmune conditions. Most people with autoimmune diseases share one thing in common: Their disease is controlled only by daily medications. It is important to keep in mind that a research breakthrough for any of the above conditions might also be beneficial for those with lupus.

In the past, I have heard arguments that too much money has been spent on research for so-called "me-too" drugs. Let me make it very clear: There is no such thing as a "me-too" drug for lupus patients. Because there is no such thing as a "me-too" patient. The truth is that a drug that works for one patient may not work for another -- even if they share the same condition. And giving lupus patients the wrong drug can cause them great physical distress or even kill them.

Let me point out a few other critical and related concerns. Appropriate medication is often determined only through trial and error. Patients frequently require combinations of medicines to bring their symptoms under control. Lupus patients also are apt to be extremely allergic, therefore they can only tolerate one or two specific drugs in a given therapeutic class. And since they must take so many other medications -- from nine to 20 pills a day is not unusual -- they must be concerned with drug interactions and dangerous side effects. Because the immune system is compromised, drug side effects can be devastating and costly. Long-term use of some steroids, for example, can cause a softening of bones and require patients to undergo costly hip and knee replacements.

What lupus patients desperately need are more medicines, more choices -- more options -- that can help them cope with their painful affliction. The one hope they have is that advanced medical research may bring a cure.

What concerns me most about the President's proposals for drug pricing is that I fear they will curtail the options available to people with lupus.

My first concern is that without continued and increased research and development, there may never be a cure. It would be tragic to create a new health-care system that discourages cost-saving medical research and denies patients new therapies and cures.

The most likely source of any future lupus cure is the biotech industry -- either by itself or in partnership with an established pharmaceutical firm. News that a small biotech company in California plans to start human clinical trials on a vaccine therapy for lupus was most heartening.

However, I fear that price restrictions, either direct or indirect, could stop that research dead in its tracks. Biotech venture capital has already dried up with the talk of price controls. Clinical trials are also being postponed.

Nor will price controls achieve long-term savings for the health-care system. Improper treatment of lupus patients can result in costly hospitalization, which certainly is more expensive than if they had received proper treatment in the first place.

We are also concerned about provisions that would limit access to the full range of medicines by forcing patients to only use generic drugs. Let me reiterate: All patients do not react the same way to the same drug. The only way to protect lupus patients adequately is to provide access to all available medical therapies.



With this in mind, let me also note our concern with recent suggestions by the Food and Drug Administration to limit so-called "off-label" uses of medications. Such an action could jeopardize the health of hundreds of thousands of lupus patients.

Currently, there is only one medication specifically approved for lupus -- prednisone. For some patients, this medicine produces the terrible side effect of crippling osteoporosis. Fortunately, certain other anti-inflammatory, anti-malarial and chemotherapy drugs have been prescribed with some success for lupus patients. Restricting their use for lupus patients would be a giant step backwards.

I do want to make it clear that we do not oppose all aspects of the Clinton Administration's reform proposal. On the contrary, we believe the plan contains several very positive components.

We strongly agree with the concept of universal coverage and portability of insurance. No one should be denied coverage because of a pre-existing condition, and no one should be afraid to leave a job for fear of losing insurance.

But I hope you will also remember that universal coverage will not succeed if chronically ill patients are denied access to proper therapies and knowledgeable physician specialists.

To sum up, I believe we are at a crossroads in history. The attention of the Congress is focused on the need for health-care reform. We have what may be a unique opportunity to improve the lives of millions of people with chronic debilitating diseases.

America has long been the leader in providing quality health care and developing new and effective medications for treating the serious diseases of our time. Let us not adopt policies that would hurt or delay research and access to proper treatment for the millions of Americans who suffer from lupus and other chronic diseases.

Thank you very much for inviting me to share my views on this extremely important topic.

Mr. WAXMAN. Ms Meyers.

# STATEMENT OF ABBEY S. MEYERS

Ms. MEYERS. As you know, Mr. Chairman, we are concerned about people with rare orphan diseases and the orphan drug problem. Just the talk of health care reform in this last year has significantly slowed the increase in all medical prices. This happens every time there is serious talk of health care reform. In the past, no bill was passed and inflation resumed where it had left off.

Last year medical price increases slowed to 5.5 percent. I want to salute the pharmaceutical industry especially, because their prices increased only 3.1 percent. Unfortunately, this is still about 15 times the overall rate of manufacturers inflation, which in 1993 was 0.2 percent. But the industry has made a good start and they deserve credit.

I want to go on record by saying we do not support price controls. We hope that the industry would police itself. Unfortunately, only 18 of the companies have made a pledge to keep their price hikes in line with inflation. And so it seems that some other mechanism is needed.

The problem is that we consumers are being cost shifted to death. Every other industrialized country in the world controls the prices of drugs. So the profits that the drug companies don't make in Europe and in other areas are cost shifted onto the American patient. That's why we are paying more for drugs than other countries.

When drug manufacturers say that they won't raise their prices higher than inflation in our country and they give discounts to bulk buyers like hospitals and HMO's, they tack the money from these discounts onto our retail prices. And when Congress mandates rebates and discounts to Medicaid, and soon Medicare, the prices go up at the pharmacy counter.

We American consumers cannot afford these escalating prices. The chain drug stores are suing the drug companies, trying to force them to provide discounts. And if what the industry says is true, if they need to make these very high profits for the sake of research and development on new drugs, then it's time for our government to tell the rest of the world that the party is over and they are just going to have to pay their fair share.

Several stipulations of the Heath Security Act should be examined and changed in regard to drugs.

First, we must have national minimum standards for formularies. If not, formularies from insurance companies all over the country will have their own rules and they will eliminate drugs based on price without any thought as to effectiveness. So the patient should be given a 72-hour emergency supply; there should be a mandatory 24-hour answer to the doctor when he requests an off-formulary drug; and there should be a prohibition against omitting drugs solely because of their price.

On the Advisory Council on Breakthrough Drugs, the law requires if a new drug is priced unreasonably, Medicare should not reimburse for it. This is absolutely unacceptable. The most vulnerable populations in the country, the elderly and disabled, need

these drugs. Why punish the patient for the prices that the companies are charging?

We have to find other mechanisms. Perhaps the determination of a reasonable price should be a role given to an existing Federal agency such as HCFA or the Department of Commerce. The determination should be based fairly on all factors, including the company's R&D and their general operating costs. And if a drug is priced unreasonably, then instead of denying it to patients, take away the company's tax credits or force compulsory licensing, which we have in other countries, which forces competition before a patent has expired. In cases of reasonably priced drugs, perhaps you could reward companies with longer patent terms.

We want the pharmaceutical industry to be strong and healthy, and they will be after everyone is insured. They won't stop developing new drugs, because that is their business. Because of Waxman-Hatch, they have to continue developing new breakthrough drugs that they can charge a premium for. Otherwise, generics will copy their whole product line and they won't be able to sell anything.

In 1992 the biotech industry raised \$2.5 billion in the stock market. In 1983, a year when health care reform was being discussed, they raised \$2.9 billion, but they had to sell more shares at a lower price in order to do it. Something should be done by the Federal Government to protect this industry and make it less reliant on Wall Street.

Thank you.

Mr. WAXMAN. Thank you, Ms. Meyers.

Mr. Perkins.

[The prepared statement of Ms. Meyers follows:]

## Testimony of

Abbey S. Meyers  
President

National Organization for Rare Disorders

Mr. Chairman, members of the Subcommittee, thank you for the opportunity to testify before you today. I am Abbey Meyers, President of the National Organization for Rare Disorders (NORD). As you know, each rare "orphan disease" affects fewer than 200,000 Americans. There are more than 5,000 of these little known but serious ailments which cumulatively effect an estimated 20 million Americans. NORD is a national non-profit voluntary health agency dedicated to the identification, treatment and cure of rare disorders.

For the past few weeks, several members of Congress have been expressing their belief that there is no health care crisis in the United States. I invite any member of Congress who doubts the validity of a "crisis" to spend one day at NORD reading the letters and listening to the phone calls we get every day of the week from ordinary people who thought they could never get sick and never lose their health insurance.

Mr. Chairman, it seems to us that the only place in our nation that *doesn't* have a health care crisis is here inside the beltway where government employees can choose from among dozens of insurance plans, and none of these plans can be canceled without warning. And, if you don't like your plan, you can change it during open season.

Not only do you not have to worry about your insurance coverage, but most of the plans offered to government employees have a prescription drug benefit. This means that you make only a small co-payment for your pharmaceuticals and are not sensitized to *real* costs of prescription drugs.

Well, outside the beltway, most Americans do *not* have a choice of insurance plans, and they cannot change insurance companies if they are not satisfied. They must take any plan their employer offers them, if they are lucky enough to have a job that provides health benefits. Insurance companies can refuse to cover you for a pre-existing condition, and can drop your coverage or quadruple your premiums if you get a serious illness. Furthermore, 64% of all Americans are without a prescription drug benefit plan.

There is immeasurable and agonizing suffering outside the beltway. There are overwhelming fears among the healthy population that at any moment they may become vulnerable to poverty and destitution if they have an accident or get a chronic disease. Because *you* -- and your staffs -- have nothing to fear from our current health care system, we are forced sit back and listen to the political rhetoric and come to the conclusion, yet again, that Congress just doesn't get it!

Gentlemen, there *is* a health care crisis and it is up to you to fix it.

In the past year, since the first discussions of health care reform began with the incoming Clinton Administration, we have seen cost increases in the health care



system slow. In fact, medical price increases slowed to just 5.4% last year. And, I especially want to commend the pharmaceutical industry for their efforts to rein in their price increases, because drug prices increased only 3.1% last year. Unfortunately, this was still 15.5 times the overall rate of manufacturers' inflation, which was only .2%<sup>1</sup>. The industry has made a good start, but it is still not good enough.

In the past I have been accused of advocating for price controls. *I would like to go on record again as saying that we do not now, nor have we ever advocated price controls.* We do believe, however, that the industry must show greater restraint in their pricing or they are going to find themselves in a position where price controls are inevitable. There should be some mechanism for pharmaceutical cost containment -- preferably by the industry itself -- with "carrot and stick" incentives from the government.

It is possible for industries to regulate themselves. The Motion Picture Industry has done it for years, and with the threat of federal legislation to limit violence we are beginning to see the rest of the entertainment industry, especially television, begin to do the same.

We are hopeful that the pharmaceutical industry is capable of regulating itself, but if they do not take the initiative themselves, then like the rest of the health care system, they will see constraints on their prices emerge from Congress. To date, 18 large PMA companies have pledged to hold their price hikes in line with inflation, but there are literally hundreds of other drug manufacturers who have made no similar pledge.

The President's Health Security Act addresses pharmaceutical cost containment in two ways: 1) by allowing every insurance company to establish a formulary and 2) by establishing an Advisory Council on Breakthrough Drugs.

As you know, a formulary is a restricted list of drugs that doctors are permitted to prescribe. On the one hand, formularies enable insurers to demand discounts on drugs because they can refuse to list a drug if the manufacturer doesn't give the insurer an appropriate discount. On the other hand, formularies can be a horrendous problem to patients who can be denied access to drugs they really need. For example, a patient can have an allergic reaction to a drug, or have no therapeutic response, but if an alternative medication is not listed on the formulary, the patient is punished for the sins of the manufacturers' pricing policies.

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<sup>1</sup>United States Senate Special Committee on Aging. *A Report on 1993 Pharmaceutical Price Inflation: Drug Prices for Older Americans Still Increasing Much Faster than Inflation.* January, 1994.

For people with rare disorders, the problem can be even more serious. Because there are so few medications developed specifically for these diseases, many ailments are treated with drugs that are not labeled for their disease. These "off label indications" are not reimbursable from many insurers, but under the President's plan they will be. Moreover, "orphan drugs" that are developed specifically for a rare disorder can be very expensive and these are exactly the types of drugs that will be omitted from many formularies solely on the basis of expense.

We believe the Health Security Act must have national *minimum* standards for formularies, and every insurer must be required to comply with those standards. These should include:

- 1) A 72-hour emergency supply of the drug to the patient when medically appropriate.
- 2) A response from the "prior authorization" panel to the doctor's request within 24 hours.
- 3) Medical foods, such as the formulas necessary to feed children with phenylketonuria (PKU), organic acidemias and other inborn errors of metabolism *must* be reimbursable and required for every formulary.
- 4) A prohibition against omitting a drug if it is the only treatment for a disease or condition. For example, Ceredase is the only treatment for Gaucher's disease, and although I have been perhaps the loudest critic of its price, it must be on every formulary. Similarly, PEG-ADA is the only treatment for "Bubble Boy Disease" and Betaseron is the only treatment for multiple sclerosis. Because of the high cost of these drugs, they are the most likely to be denied inclusion on formularies, but then it would simply be inhumane to exclude them.

Additionally, we would suggest that the law should require outcomes research to be done on the cost effectiveness of prescription drugs.

The second area where the President's Health Security Act addresses drug prices is the Advisory Council on Breakthrough Drugs.

We believe that Americans should not pay more for pharmaceuticals than other industrialized countries. The industry says they need to make large profits in order to support research on new drugs, and we agree. But it is time to tell the rest of the world that the American consumer can no longer afford to underwrite the world's pharmaceutical research effort. There is no better way to get this message across to other nations than to say we won't pay more than the average price paid in industrialized nations that share the same living standards.

However, we have a deep concern about the proposal to give the Advisory Council on Breakthrough Drugs the power to decide that if a manufacturers' price is not reasonable in the United States, Medicare will not reimburse for the drug.

Medicare is the insurance system available to two of the most vulnerable segments of our society -- the disabled and the elderly. These populations are the highest users of prescription drugs. If Medicare does not purchase a breakthrough drug because its price is unreasonable, who will be punished? The manufacturer or the patient? By far the patients will suffer more than the manufacturer, Mr. Chairman, so we would like to see another mechanism developed to solve this problem.

Perhaps the Council, or any other agency of government charged with reviewing the fairness of drug prices (such as HCFA), can devise a formula which could reduce or deny some corporate tax credits if a company's drug is priced unreasonably. Or perhaps "compulsory licensing" could be utilized as it is in other nations; a company would be required to compete with a mandatory licensee if the government determines that it is justified. And, when brand name drugs cost substantially more than generic drugs, health insurance should reimburse for the generic price which would require patients to pay the difference themselves (except in certain cases such as epilepsy that can be outlined in the law). Maybe an incentive for reasonably priced drugs could also be introduced. Grant the public minded corporations who charge reasonable prices extra years of exclusivity or lengthen their patents.

Finally, Mr. Chairman, I want to state clearly our feelings and opinions of the American pharmaceutical industry. We stand in awe of its research prowess, and we need the industry to stay prosperous and productive. Our lives depend on its success. We understand the industry's concerns about price controls because this is the last free market in the world, and they want to keep it that way.

However, the fact is that during the last decade, and even now their price increases have far outpaced the CPI *and* the PPI. They have spent too much money and time developing "me-too" drugs. In their race to beat their competitors, they have instituted egregious marketing tactics and they have perhaps lost touch with their customers: the American patient. They have created a spiral of unnecessary increasing costs which of course had to be translated into increased prices and on and on. And when we talk about reasonable prices they threaten that they won't develop new life saving therapies if they can't continue to make unlimited profits. This is like a child holding its breath, threatening not to breathe if it doesn't get its wish.

We believe, Mr. Chairman, that the industry is not blind to its self-created problems. We see company after company using the current reform climate to justify downsizing their bloated sales forces, and refocussing their R&D. Many industry financial analysts agree that these are positive outcomes from what is perceived as a negative, anti-industry mood in government and the backlash of public opinion, and I agree. We see

the brand name industry, while mistakenly defending its past practices, attempting to right itself and get back on course. And we hope it will.

The biotech segment of the pharmaceutical industry is in a different situation, and should not be wrapped in the same cloak as the older pharmaceutical firms. First of all, this industry is young and is fragile. While it holds great promise it's like a young athlete who has good games and bad games. Industry leaders tell us that the threat of the proposed Advisory Council on Breakthrough Drugs has had a serious impact on their ability to raise investment capital.

Of course, this is only *one* factor affecting their fundraising: The industry's continued problems getting new products approved, their relatively few successes compared to the number of failures, the over optimistic forecasts in their annual reports -- these factors also hurt them.

But, the point is, we all agree this is an extremely important industry. It is at a critical stage of development, and it needs to be nurtured. We ought to take a lesson from the Japanese who learned how to target a business sector for development through subsidies and protection, and propel it toward world dominance.

That is not to say they should have free license to price their drugs as high as the market will bear. We continue to be critical of companies that have abused their orphan drug exclusivity by charging our patients outrageously high prices, and we will continue to speak out when we see such abuses.

But, we want this industry to grow and thrive, while showing social responsibility, too.

I sense that Congress has the same objective, because we are all hoping that somehow competition and free market principles will impose the leverage on prices that will keep medical goods and services affordable, but at the same time keep our industries healthy. Again, we do not support price controls, but changes in our current system are desperately needed to make the free market work for consumers, not only the patients who need pharmaceuticals, but all the healthy Americans and their employers who pay for health insurance premiums. Continuation of our current policies, or lack of policies in the medical marketplace would be foolhardy, because medical inflation will bankrupt the nation if it continues to run unchecked.

Now that we are seeing a genuine willingness of large segments of the pharmaceutical industry to comply with the reality of the American economy, we think Congress ought to give the industry the benefit of the doubt and see how the free market responds during the first few years of health care reform. If they cannot police themselves, and if their prices rise higher than the annual CPI, then Congress should revisit the issue of cost containment. Meanwhile, a series of incentive and disincentives such as the capability to withhold tax credits might suffice.



In conclusion, Mr. Chairman, I would just like to say again that there ~~is~~ a health care "crisis" out there, and we Americans want what you and your staffs have -- health care security. You and the rest of the members of this great institution can solve this crisis by passing the Health Security Act, and including in it a national minimum standard for formularies and creating a mechanism that will assure reasonable prices for new pharmaceuticals that is fair to manufacturers, fair to insurers and fair to consumers. We also implore you to add genetic testing and counseling and refocus some of the language from acute care needs to address chronic health conditions.

We Americans simply can no longer afford to subsidize the rest of the world's drug prices, nor can we continue to pay the industrialized world's tab for research and development of new drugs. Nor can we patients afford to subsidize the discounts given to large bulk buyers, through the higher prices we pay at the retail pharmacy.

The American taxpayer should not subsidize manufacturers of unreasonably priced drugs through corporate tax credits and patents. And you should take this opportunity of reform to restrict inappropriate and lavish marketing practices that add to our health care costs. The pharmaceutical industry should earn a competitive rate of return on their investments, no more and no less. But, most of all, Mr. Chairman, by the end of this Congressional session, you **MUST** ensure that health care is affirmed as a human right and not a privilege.

Thank you.

**STATEMENT OF JOSEPH PERKINS**

Mr. PERKINS. Good afternoon. I'm Joe Perkins, a member of the Board of Directors of AARP. I want to thank you for inviting AARP to testify on the prescription drug benefit.

AARP is a strong advocate of comprehensive health care reform that provides universal coverage, and we firmly believe that any viable reform proposal must include a universal drug benefit.

Today 70 million Americans lack drug coverage. That means too many people are being denied access to essential, often life sustaining drugs.

This problem is most severe for older Americans as the combined effects of high prices, heavy utilization, and the absence of affordable insurance coverage has significantly reduced their access to needed medicines. AARP is pleased that the President's plan includes a drug benefit for all Americans and addresses the special needs of older Americans by expanding Medicare to cover prescription drugs.

I would like to review the President's proposal in the context of six basic elements that we believe must be part of any drug benefit.

The first one is guaranteed access. AARP is extremely concerned about the affordability of prescription drugs, particularly for older Americans. A 1992 study shows that older Americans use significantly more prescription drugs than other age groups to maintain their health.

Prescription drug insurance coverage declines rapidly as age increases, as you can see in the bar chart off to my left. You will notice that those age 75 and older, only 40 percent of them have coverage.

Out-of-pocket costs for prescription drugs are significantly higher for older Americans.

The President's plan would ensure access to prescription drugs, especially for older Americans, who are the most vulnerable.

Second, there must be effective cost containment as part of any drug benefit or the benefit may quickly become unaffordable. As you recall, Mr. Chairman, this was clearly the case during the development of Medicare Catastrophic Coverage Act. Due to the lack of effective cost containment, the projected costs of the drug benefit skyrocketed even before the bill made its way through the conference committee.

We believe the President's plan incorporates effective cost containment while retaining adequate incentives for research and development and ensuring access for beneficiaries.

Other forms of cost containment may be effective as well, but we believe that cost containment should not impede beneficiary access to needed medications or pharmacy counseling. I must say we view the voluntary price restraint proposal advocated by the pharmaceutical industry as entirely inadequate, as it does little to help cash paying consumers, who very definitely, we feel, are the most vulnerable.

We are all familiar with the argument made by the industry in the high priced full page ads that every dollar you seek in cost containment will come directly out of research and development of important breakthrough medications. Mr. Chairman, this is a clear

case of false and misleading advertising, we believe. Much more goes into the price of a drug than R&D.

If you take a look at the pie chart on my left, you will see that only 16 percent of the manufacturers' price of a drug goes towards R&D compared to the 36 percent that goes towards marketing and advertising and profit. We believe the industry could bring its profits down to a more reasonable level and cut back on excessive promotional activities without harming R&D.

The third point is financing. We believe the Medicare premium should cover approximately 25 percent of program costs, similar to what is already now in current part B financing. The President's plan does this with a stated \$11 premium, but Dr. Lee this morning said it might be even as low as \$9.

We are concerned, however, that the President's plan would fund the drug benefit largely through substantial cuts in Medicare. Cuts of this magnitude could create quality and access problems for beneficiaries, and we are concerned about that, very definitely.

Fourth point. We believe that the structure of the drug benefit for Medicare beneficiaries should be parallel to that for those under age 65. And that will be very important. The President's plan largely achieves this but it's important to generate support for reform among older Americans to have that.

Fifth point. There must be special protection for all those of low incomes, which the President's plan has only for those under the age of 65. We believe that equal protection should be extended to low income Medicare beneficiaries.

A sixth point. To reduce the incidence of adverse drug reactions, over-medication, inappropriate prescribing, the drug benefit should include an effective drug utilization review program that focuses on prevention education.

Mr. Chairman, we want to thank you for allowing us to be here. We want to work with you to make sure there is a proper and working passage of a comprehensive health act.

Thank you.

Mr. WAXMAN. Thank you very much, Mr. Perkins.

[Testimony resumes on p. 613.]

[The prepared statement of Mr. Perkins follows:]

STATEMENT  
of the  
AMERICAN ASSOCIATION OF RETIRED PERSONS

Good morning, Mr. Chairman, and members of the subcommittee. I am Joseph Perkins, a member of the Board of Directors of the American Association of Retired Persons (AARP). AARP appreciates the opportunity to testify today on the prescription drug benefit provisions included in President Clinton's Health Security Act. AARP is a strong advocate of comprehensive health care reform that will provide universal coverage, and we firmly believe that any viable health care reform proposal must include a universal prescription drug benefit.

While AARP has not yet endorsed any specific health care reform plan, we believe the President's proposal provides the strongest and most realistic blueprint to date for achieving our goals. In particular, we share the President's commitment to assure all Americans affordable and comprehensive coverage for prescription drugs. Currently, about 70 million Americans lack prescription drug coverage, and those who cannot afford to pay for their medications out-of-pocket are too frequently denied access to essential, often life-saving drug therapies. This can compromise their health status and make them more likely to receive unnecessary and more expensive care.

This problem is most severe for older Americans as the combined effects of high prices, heavy utilization, and the absence of affordable insurance coverage for prescription drugs have substantially reduced their access to needed drug therapies. In this regard, AARP is pleased that the President's proposal includes a prescription drug benefit for all Americans and addresses the special needs of older Americans by expanding the Medicare program to cover outpatient prescription drugs.



Our testimony will review the President's proposal in the context of the basic elements of a drug benefit that we believe must be part of any viable health care reform plan. These elements include:

- guaranteed access to needed drug therapies;
- effective cost containment;
- stable, broad-based, and equitable financing;
- a parallel benefit structure across all ages;
- protections for low-income beneficiaries; and
- provisions that encourage appropriate prescribing, monitoring, and use of medications.

### **Guaranteed Access**

AARP is committed to expanding access to quality, affordable health care. To this end, we have developed a health care reform proposal called "Health Care America," which guarantees access to health and long-term care services for all individuals and includes coverage for prescription drugs. We view our proposal as both a vision statement for the Association and a standard for evaluating other reform proposals.

In regard to prescription drugs, we are extremely concerned about the lack of access, particularly among older Americans. A 1992 survey sponsored by AARP showed that:

- older Americans use significantly more prescription drugs than other age groups to maintain their health;
- prescription drug insurance coverage declines rapidly as age increases (see Chart I); and
- out-of-pocket costs for prescription drugs are significantly higher for older Americans than for their younger counterparts.

As a result, many older Americans cannot afford high prescription drug prices and are too frequently denied access to essential, often life-saving, medications. Fifty-eight percent of older Americans surveyed reported that, compared to other health care costs, they had a problem paying for their prescriptions; over half of these said it was a major problem. Moreover, about ten percent said they had to cut back on necessary items, such as food and heating fuel, to afford their medications.

The prescription drug benefit provisions in President Clinton's Health Security Act would ensure access to important, health-sustaining drug therapies to all Americans, especially those who are most vulnerable to losing access today -- older Americans. We are pleased that the President's proposal addresses the special needs of older Americans by including a meaningful Medicare drug benefit. As you know, the Association has been a long-standing advocate for expanding Medicare to cover outpatient prescription drugs.

We look forward to continuing to work with you and your colleagues to ensure that a prescription drug benefit that guarantees access to needed drug therapies is a part of the health care reform proposal that emerges from this subcommittee and other committees in the House and Senate.

### **Effective Cost Containment**

AARP strongly believes that effective cost containment must be part of any prescription drug benefit. If effective cost containment is not included, the benefit may quickly become unaffordable to both taxpayers and beneficiaries. As you will recall, this was clearly the case during the development of the Medicare Catastrophic Coverage Act (MCCA). Due to the lack of effective cost containment, the projected cost of the MCCA drug benefit (and the resulting estimates of premiums to be paid by beneficiaries) skyrocketed even before the bill made its way through the conference committee.

We believe the President's proposal does include effective cost containment mechanisms. For non-Medicare beneficiaries, the President's plan would rely primarily on private sector competitive price negotiating mechanisms currently used by many hospitals, HMOs and other large purchasers to contain prices. In addition, formularies, generic substitution, and drug utilization review are mechanisms that health plans could use to contain prescription drug costs. Given the success of these various mechanisms for containing prescription drug costs, AARP believes that health plans under the President's proposal would have a strong incentive to use similar techniques to contain drug costs.

The President's proposal would also help health plans make informed decisions on the potential role of "breakthrough" drugs (new drugs which represent a significant advance over existing therapies and, therefore, have little or no competition) through an "Advisory Council on Breakthrough Drugs." The Council would be responsible for:

- 1) reviewing the launch prices of breakthrough drugs;
- 2) reporting on the cost-effectiveness and therapeutic value of these new products; and
- 3) determining whether the price is reasonable based on such factors as the price charged in other countries, cost information supplied by the manufacturer, and projected sales volume.

AARP believes that the activities of this council are essential given that individual health plans would have difficulty evaluating the appropriateness of prices for new drug therapies on their own.

For Medicare beneficiaries, the President's proposal would contain drug costs largely through payment limits that encourage the use of generic drugs and through rebates required from manufacturers. AARP has always encouraged the use of generic drugs as a way to significantly reduce out-of-pocket costs for needed medications. Consumers generally pay 30 to 50 percent less for generic equivalents of brand name drugs. Under the President's

proposal, unless a brand name drug were specifically prescribed by the physician, Medicare would only pay the pharmacist the cost of the generic substitute, thereby giving the pharmacist an incentive to dispense generic drugs. AARP believes this provision provides a reasonable and effective way to control drug costs under the Medicare program.

In addition, the President's proposal would establish three types of rebates that drug manufacturers could potentially pay to Medicare:

- 1) a basic rebate equal to 17 percent of the average manufacturers retail price (AMRP) or the difference between the AMRP and the price paid by non-retail purchasers (e.g., hospitals and HMOs), whichever is greater;
- 2) an inflation rebate paid by manufacturers for each drug whose retail price increases faster than the general inflation; and
- 3) a special rebate that is negotiated by the Secretary of Health and Human Services (HHS) for a new drug that is determined to be excessively priced.

AARP firmly believes that these rebate provisions would provide an effective and reasonable way to contain prescription drug costs for the Medicare program while retaining adequate incentives for research and development. Given the enormous purchasing power of the Medicare program, we believe Medicare should receive discounts comparable to those manufacturers provide to other major purchasers. In this regard, a recent study by the Boston Consulting Group for the pharmaceutical industry showed that the average private market discount in 1992 was about 16 percent, and that more than half of the U.S. pharmaceutical market received discounts of greater than 25 percent. As a result, we believe that a minimum basic rebate of 17 percent for Medicare, as proposed by the President, is reasonable.



In addition, given that prescription drug prices in the United States have increased at nearly three times the rate of inflation over the past twelve years, we believe that the Medicare inflation rebate proposed by the President is necessary to restrain excessive price increases in the future. This rebate would also help to stop manufacturers from gaming the system by inflating their prices to compensate for the cost of the basic rebate.

Moreover, to assure that Medicare reimbursement for new drug products is reasonable, AARP believes that the special rebate provisions included in the President's plan are warranted. In negotiating this rebate with manufacturers, the Secretary would have to consider a number of factors including the prices of other drugs in the same therapeutic class, cost information from the manufacturer, and the prices of the drug in other industrialized countries. AARP believes that this provision will ensure that Medicare is paying fair and reasonable prices for new drugs that offer meaningful improvements over existing products.

Although AARP believes the President's proposal employs a reasonable approach to cost containment while retaining adequate incentives for research and development, other cost containment mechanisms may be effective as well. For example, a few major pharmaceutical manufacturers are offering potentially meaningful alternatives for providing drug coverage to Medicare beneficiaries while controlling costs. At the same time, AARP believes that such cost containment mechanisms should not impede convenient beneficiary access to needed medications or pharmacy counseling. Although we have not seen the details of these alternative proposals, we have expressed a willingness to review them. We recognize that cooperation from the industry could help to expedite Congressional action on this important benefit.

Unfortunately, the leading Association for the pharmaceutical industry has not shown a willingness to cooperate in developing effective cost containment provisions. Instead, it continues to insist that every dollar in revenue reduced by policymakers' efforts to contain

drug prices will come directly out of research and development of important breakthrough medications.

AARP believes that this is simply false. Much more than legitimate research and development activities go into a manufacturer's price of a drug; therefore, a drug manufacturer has many choices as to where it can be more efficient and cut costs. In fact, according to a 1993 study by the Senate Special Committee on Aging, only 16 percent of the manufacturer's price of a drug goes toward research and development compared to the 36 percent that goes toward profits, marketing, and advertising (see Chart II). In addition, estimates based on a recent Office of Technology Assessment report indicate that during the 1980s pharmaceutical companies on average earned about 15 to 30 percent more profit each year than needed to attract adequate investment in capital.

Given this, AARP believes the industry could accept profits of a more reasonable level and eliminate excessive promotional activities without harming legitimate research and development endeavors. Moreover, because research and development is the lifeblood of the pharmaceutical industry, it is most likely the last area manufacturers would look to cut.

AARP is also concerned about the "voluntary" price restraint proposals currently advocated by the pharmaceutical industry. The industry claims that its "voluntary" efforts are working and backs its claim by citing the Producer Price Index (PPI) for pharmaceuticals, which was 3.1 percent in 1993. According to a Senate Special Committee on Aging report released last week, however, drug manufacturer price inflation at the retail level -- where most older Americans buy prescription medications -- continued to increase much faster than general inflation in 1993. In fact, according to the report, "forty of the top 200 drugs increased in price at the retail level more than twice the rate of general inflation, which was 2.7 percent in 1993."

Clearly voluntary cost containment is entirely inadequate and merely perpetuates cost shifting from the inpatient market, where HMOs and hospitals negotiate deep discounts from

manufacturers, to the outpatient or retail market, where similar discounts are not offered. AARP is pleased that the President's proposal includes provisions which would reduce such cost shifting, particularly to the retail sector of the market.

### **Stable, Broad-Based, and Equitable Financing**

AARP believes that the financing for a Medicare drug benefit should come from a combination of reasonable premium payments by beneficiaries as well as other stable, more broad-based, and equitable sources. To the extent that a Medicare drug benefit is financed through an increase in the Medicare Part B premium, we believe the increase should be consistent with Part B financing, in which premiums currently constitute approximately 25 percent of program costs.

AARP is pleased that the President's proposal takes this approach. The Administration estimates that the Medicare monthly premium in 1996 would increase by \$11 (from \$50.20 to \$61.20) to cover prescription drugs. We believe this is a reasonable amount, and recent AARP polling information shows that the majority of Medicare beneficiaries would support such an increase. We would note, however, that Medicare beneficiaries are currently paying high out-of-pocket costs, and premiums that grow much beyond this amount could become burdensome to many beneficiaries. We believe the best way to ensure reasonable premium levels is through effective cost containment mechanisms that keep the benefit affordable.

According to Administration estimates, the cost of the Medicare drug benefit, after taking into account both premiums and rebates, is \$66 billion over five years. Unfortunately, the Administration's proposal does not include any broad-based sources of financing to cover these costs. Instead, although not explicitly stated in the legislation, the Administration intends to pay for the Medicare drug benefit, as well as the Home and Community-Based Care program, largely through significant cuts in the Medicare program totalling \$124 billion over five years. These cuts come on top of the \$56 billion in Medicare cuts enacted last

August in the 1993 budget reconciliation act. We are extremely doubtful that the Medicare program could sustain such enormous reductions without creating quality and access problems for beneficiaries.

In addition, AARP believes that additional limitations on Medicare reimbursement levels alone will do little to either slow the overall rate of health care cost growth in the economy or provide a long-term solution to the budget deficit unless private sector health care spending is also limited. The President's proposal includes premium limits to slow the growth in health care costs in the private sector, and AARP generally supports this approach. In the absence of system-wide cost containment, however, AARP would strongly oppose further Medicare cuts -- especially large-scale cuts such as \$124 billion.

AARP realizes that these proposed Medicare savings, even if they can be achieved, are not a broad or permanent source for financing health care benefits. We would like to work with members of this subcommittee and others in the Congress to identify alternative sources of financing that offer a more stable, broad-based, and equitable means of financing a Medicare drug benefit as well as other essential benefits included in health care reform.

#### **Parallel Benefit Structure for Medicare and Non-Medicare Beneficiaries**

AARP strongly believes that the structure of a prescription drug benefit for those age 65 and older should be parallel to the structure of the benefit for those under age 65, specifically with regard to cost-sharing requirements. We believe the President's proposal largely achieves this by making the Medicare annual drug deductible and coinsurance of \$250 and 20 percent, respectively, equivalent to those required for non-Medicare beneficiaries in a fee-for-service plan.

We believe the \$250 deductible is reasonable because the majority of Medicare beneficiaries will exceed it and, thereby, be better able to afford their medications. As you will recall, the



prescription drug deductible included in the MCCA was set at a level where only 16.5 percent of Medicare beneficiaries would receive benefits. Given that a majority of older Americans report having problems paying for their medications, we believe that the deductible proposed by the President will better ensure access to needed medications.

In addition, AARP believes that a 20 percent coinsurance for prescription drugs would not be excessively burdensome to most beneficiaries and would provide protection against prescription drug costs that is comparable to that for physician services under Part B. We are also pleased that the President's plan includes an out-of-pocket limit of \$1,000 per year on beneficiary spending for prescription drugs. This out-of-pocket limit will be a great financial relief for beneficiaries who would otherwise spend extraordinary amounts on medications to maintain their health. The President's plan, however, does not include an out-of-pocket cap for all other Medicare services but does include one for alliance plans. We firmly believe that total out-of-pocket expenses for Medicare beneficiaries should also be capped because older Americans currently pay the highest out-of-pocket expenses for medical services.

AARP would like to work with the Congress to ensure that a parallel structure in a prescription drug benefit between Medicare and non-Medicare beneficiaries be retained as it will ultimately be very important in generating support among older Americans.

### **Low-Income Protections**

In order to ensure that individuals of all ages have access to necessary medications, AARP firmly believes that health care reform must include special protections for those with low incomes. We are particularly concerned about the roughly 10 percent of Medicare beneficiaries who are too poor to afford Medigap coverage but are not poor enough to qualify for Medicaid or the Qualified Medicare Beneficiary (QMB) program. The QMB program pays Medicare premiums and all Medicare cost-sharing for persons below the

poverty level, but pays only the Part B premiums for those between 100 and 120 percent of the poverty level.

The President's plan would provide federal subsidies for premiums and coinsurance for individuals up to 150 percent of poverty -- but only for those under the age of 65. AARP strongly recommends that health care reform legislation offer equal protections for low-income Medicare beneficiaries so that unmanageable drug costs do not continue to be a barrier to accessing needed medicines.

### **Appropriate Prescribing, Monitoring, and Use**

A recent RAND Corporation review estimated that more than 40 percent of prescriptions for those age 65 and over are inappropriate. The adverse reactions that can result from inappropriate prescribing can lead to drug-induced illnesses, hospitalization, and even death, not to mention unnecessary and wasteful health care expenditures. To reduce the incidence of mismedication, overmedication, and other inappropriate prescribing practices, AARP believes that any prescription drug benefit should include an effective drug utilization review (DUR) program that includes the following features:

- **Prevention**: The DUR program should include an on-line computerized prospective review of prescriptions at the point of purchase to immediately identify potential problems for the patient and to assure that prescribed medications are appropriate and will not cause adverse medical results (e.g., adverse drug-to-drug interactions).
- **Education and Enforcement**: The DUR program should include an educational component that requires pharmacists to offer to counsel Medicare beneficiaries on proper use of their medications, potential side-effects, and any other potential

problems. In addition, the DUR program should include a retrospective component that identifies inappropriate prescribing practices by physicians and provides feedback to physicians to encourage appropriate prescribing. The program should also identify patterns of fraud and abuse among physicians, pharmacists, and patients.

- Standards: A National Commission on Drug Use Review should be established to set standards and criteria for DUR under the program. The Commission should include consumer representation.

Although AARP is pleased that the President's proposal incorporates a variety of quality assurance mechanisms, we are very concerned that it does not require DUR and that pharmacists are not required to offer counseling to patients. We strongly believe that these provisions are essential to ensuring improved prescribing by physicians and dispensing by pharmacists, and ultimately, better safety for patients.

AARP would like to work with the Congress to ensure that a Medicare drug benefit does not simply make prescription drugs more accessible to Medicare beneficiaries but also takes appropriate steps to ensure that medications are taken safely and wisely.

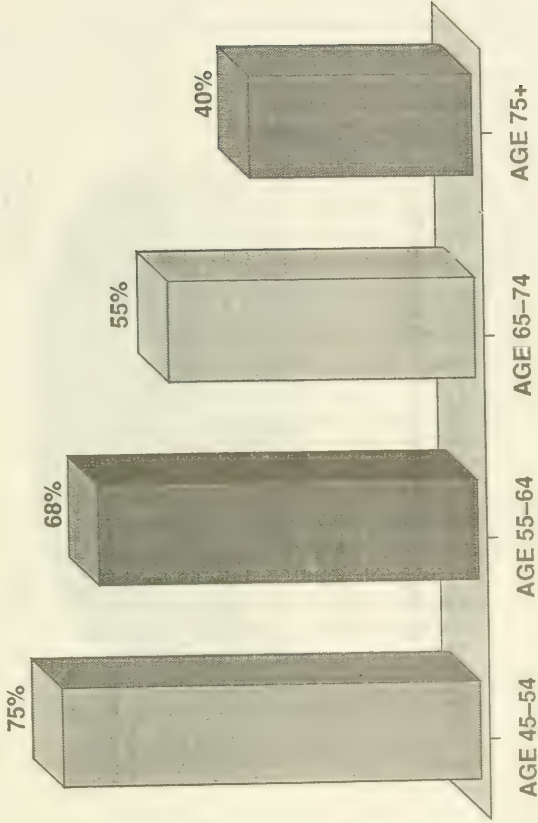
### Conclusion

AARP is a strong advocate of comprehensive health care reform that includes prescription drugs as a benefit for all Americans. We believe that any prescription drug benefit included under a reformed system must: 1) guarantee access to needed drug therapies; 2) contain costs effectively; 3) rely on stable, broad-based, and equitable financing; 4) provide for a parallel benefit structure across all ages; 5) protect low-income beneficiaries from exorbitant costs; and 6) encourage appropriate prescribing, monitoring, and use of medications.

We are pleased that the President's prescription drug benefit provisions incorporate most of these important elements, and we look forward to working with members of this subcommittee and others in the Congress to ensure that these provisions are included in health care reform.

# Percent Having Prescription Drug Coverage

CHART I

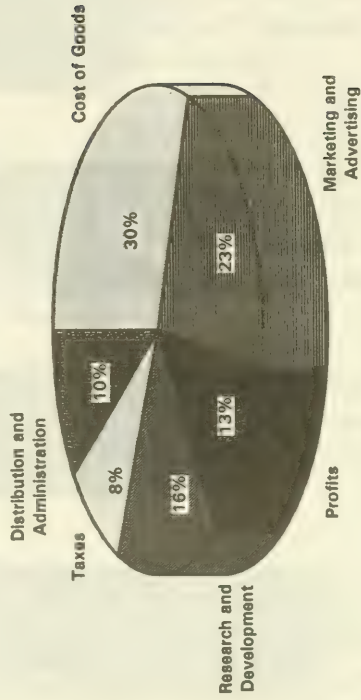


Source: "The Need for a Prescription Drug Benefit Under the Medicare Program," prepared for AARP by Chilton Research Services, June 1992.



Chart II

## Where the U.S. Prescription Dollar Goes (Manufacturers Component)



**STATEMENT OF DANIEL PERRY**

Mr. PERRY. Thank you. Chairman Waxman, Congressman Wyden, and distinguished members of the subcommittee, I am pleased to address the likely impact of the Health Security Act on the quality of health care available to older Americans now and in the future.

The Alliance for Aging Research is an independent, nonprofit organization working to stimulate academic, governmental and private sector research in the chronic diseases of aging.

We agree that health care coverage and delivery needs fixing as America braces for the unprecedented aging of our population. Our organization believes it's an outrage that some older Americans have been forced by poverty to choose between food and the medicines they need. Therefore, we support prescription drug benefit within the Medicare program. But it will be just as tragic if older people are required to choose between cheap drugs that only mask the symptoms of chronic disease and the vastly more effective medicines that will come from ongoing biomedical research.

Investments in research and active collaborations between publicly and privately funded research have produced revolutionary new understandings of human biology in the past 30 years. As a result of this unique partnership, the American research enterprise is the envy of the world for encouraging intellectual freedom and for producing effective new diagnostics, medical devices, and therapies.

Our present strong science base and robust public-private research enterprise is just what the United States will need as we prepare for our future as an aging society. The costs of untreated diseases with an aging population are staggering. Already just eight age-related afflictions for which there are no known cures cost the United States a total of \$431 billion a year, or nearly half the total annual U.S. bill for health care.

Imagine the costs of health care in 30 years if, lacking newer and better ways to treat, prevent or postpone these diseases, we face 4 or 5 times today's costs of caring for our oldest citizens. Without breakthroughs from research and access to safe and effective new therapies for the elderly, we could face a 21st Century explosion of old age diseases and chronic disabilities with nothing better than late 20th Century palliative health care, pain killers and nursing homes. We estimate that right now the United States would save \$5 billion in health care and custodial costs for each 1 month we might delay the loss of independence among the elderly.

Despite this promise, most of the debate and legislative proposals regarding health care largely ignore or disparage research. It may be that sustaining the current high productivity in biomedical research is on a collision course with short-range cost containment goals. If so, we should be honest with the American people. Some of the proposals now on the table might freeze the development of new medicines by controlling introductory prices of new drugs or by limiting patient access to new therapies.

It seems particularly perverse to the Alliance for Aging Research that the Health Security Act would rely on market competition and the buying power of health alliances to restrain prescription drug prices for people under age 65 but it would set up semi-price con-

trols within the Medicare prescription drug benefit and aim them directly at the newer and more effective drugs that the elderly so urgently need.

The American people place a very high premium on hope for new cures and better means of prevention. A Louis Harris poll released in December found that 91 percent of Americans believe that we should spend more on medical research, and the vast majority want a lot more research. My own organization surveyed more than 900 people and found 8 out of 10 want any type of health reform to include more government emphasis on medical research to cure and prevent diseases.

Reducing the need for expensive hospital stays, operating rooms and nursing homes on a large scale is indeed possible, but only if we achieve a deeper understanding of the interplay of human genetics, environmental risks, including behavior, and of aging.

Regrettably, we have not seen a commitment in that direction in current health reform proposals, and some aspects of the Health Security Act could take us in the opposite direction. The Alliance urges the subcommittee to affirm a commitment to research, discovery and biomedical innovation. The Health Security Act will be strong if it does not create disincentives for medical research so important for the health of today's older Americans and those who will follow.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you very much, Mr. Perry.

[The prepared statement of Mr. Perry follows:]

STATEMENT OF DANIEL PERRY, EXECUTIVE DIRECTOR, ALLIANCE FOR AGING RESEARCH

Chairman Waxman, Congressman Bliley, and distinguished members of the subcommittee, I am pleased to address today the likely impact of the Health Security Act on the quality of health care available to older Americans now and in the future. The Alliance for Aging Research is an independent, non-profit organization working to stimulate academic, government and private sector research in the chronic diseases of aging. We seek to address the public interest in advancing scientific research, prevention and health care training to improve health and vitality for all people as they age. The Alliance has carefully examined the Health Security Act and other reform proposals from this perspective.

We agree that health care coverage and delivery needs fixing as America braces for the unprecedented aging of our population. The Alliance applauds the emphasis the Clinton administration has given health care issues. We particularly support greater emphasis on primary care, the beginnings of more rational public support for long term health care, and insurance coverage for prescription drugs. We believe it is an outrage that some older Americans have been forced by poverty to choose between food and the medicines they need. Therefore, we support a prescription drug benefit within the Medicare program. But it will be just as tragic if older people are required to choose between cheap drugs that only mask the symptoms of chronic disease and the vastly more effective medicines that will come from on-going biomedical research.

While moving towards reform, we must not do harm to the best of American health care that now exists. Clearly the public's investment in biomedical research, together with a private sector investment climate that encourages risk and innovation, have brought us advances that define our current high standards of medical practice. Investments in research and collaborations between publicly- and privately-funded research have produced revolutionary new understandings of human biology in the past 30 years. The American research enterprise is the envy of the world for encouraging intellectual freedom and producing effective new diagnostics, medical devices and therapies. Half of the world's major new drugs discovered in the past 15 years have originated from U.S. pharmaceutical and biotechnology companies in collaboration with publicly-supported researchers.



A strong science base and a robust public-private enterprise are America's aces in the hole in preparing for our future aging society. We are a Nation in which 6,000 more people every day celebrate their 65th birthday. While most of us can look forward to healthy active senior years, the risks rise sharply with age for a host of life-destroying chronic illnesses including Alzheimer's disease, osteoporosis, stroke, diabetes, cancer, arthritis and age-related loss of both hearing and sight. The costs of untreated diseases with an aging population are staggering. Already just eight age-related afflictions for which there are no known cures cost the United States a total of \$431 billion a year or nearly half of the total annual U.S. bill for health care.

Imagine the costs of health care in 30 years if, lacking newer and better ways to treat, prevent or postpone these diseases, we face 4 or 5 times today's costs of caring for our oldest citizens. Without breakthroughs from research and access to safe and effective new therapies for the elderly, we could face a 21st Century explosion of old age diseases and chronic disabilities with nothing better than late 20th Century palliative health care, pain killers and nursing homes. We estimate that right now the United States would save \$5 billion in health care and custodial costs for each 1 month we might delay the loss of independence among the elderly.

Despite this promise, most of the debate and legislative proposals regarding health care largely ignore or disparage research. It may be that sustaining the current high productivity in public and private biomedical research is on a collision course with short-range cost-containment goals. If so, we should be honest about this with the American people. Some proposals now on the table might freeze the development of new medicines by controlling introductory prices of new drugs or by limiting patient access to new therapies.

It seems particularly perverse to the Alliance for Aging Research that the Health Security Act would rely on market competition and the buying power of the health alliances to restrain prescription drug prices for people under age 65, but it would set up price controls within the Medicare prescription drug benefit and aim them directly at the newer and more effective drugs that the elderly so urgently need. The Alliance has taken its concerns directly to the Clinton administration regarding the proposed breakthrough drug committee and the blacklisting authority for new drugs.

We find these proposals especially troubling because they coincide with flat or declining budgets for most medical research at the National Institutes of Health, the Department of Veterans Affairs and other research agencies and with dwindling support for research training. Measures that depress investment in new medical technologies, that discourage young investigators from pursuing careers in research, that provide too little support for academic health centers, that inhibit the free transfer of technology from laboratory to the marketplace, all these put current health reform proposals on a collision course with research and with the future.

The American people place a very high premium on hope for new cures and better means of prevention. A survey by Public Pulse found of all the sacrifices Americans might endure for health care reform, the one that 70 percent would not tolerate is a delay in development of new technologies and drugs. A Louis Harris poll released in December found that 91 percent of Americans believe that we should spend more on medical research, and the vast majority want "a lot" more research. The Alliance for Aging Research surveyed more than 900 people and found 8 out of 10 want "any type of health reform to include more government emphasis on medical research to cure and prevent diseases."

Perhaps more than any other component of our health care system, innovation and research in medicine hold the ultimate hope of both reducing health care costs and improving quality of care as well as the quality of life. Reducing the need for expensive hospital stays, operating rooms and nursing homes on a large scale is indeed possible, but only if we achieve a deeper understanding of the interplay of human genetics, environmental risks including behavior, and of aging. This calls for a national commitment to fostering innovation in prevention and in biomedical research as a major goal of national health care reform.

Regrettably, we have not seen that commitment in current health reform proposals, and some aspects of the Health Security Act could take us in the opposite direction. The Alliance urges the subcommittee to affirm a commitment to research, discovery and biomedical innovation. The Health Security Act will be stronger if it does not create disincentives for medical research so important for the health of today's older Americans and those who will follow.

We believe these proposals, if enacted, could cause America to lose the promise of the modern Biology Revolution and do serious harm to the Nation's ability to assure quality of health care in the future.



Mr. WAXMAN. Dr. Yaffe.

**STATEMENT OF SUMNER J. YAFFE**

Mr. YAFFE. I am Sumner Yaffe, Director of the Center for Research for Mothers and Children of the National Institute of Child Health and Human Development at the National Institutes of Health. My special expertise is in the use of drugs with infants and children.

I am pleased to have an opportunity to appear before you, not to offer testimony—that has been presented by Dr. Lee—but to answer any questions you might have regarding the use of drugs in this very special population.

[Testimony resumes on p. 630.]

[The prepared statement and commentary of Dr. Yaffe follow:]

## STATEMENT BY

SUMNER J. YAFFE, M.D.

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Chairman Waxman and members of the Subcommittee:

I am Sumner Yaffe, the Director of the Center for Research for Mothers and Children of the National Institute of Child Health and Human Development (NICHD) at the National Institutes of Health (NIH). My special expertise is in the use of drugs with infants and children. My interest in this area developed while pursuing graduate studies in pharmacology at the Harvard Medical School. This interest persisted throughout medical school and my post-doctoral training in pediatrics. I continued my research on drug action and disposition in infants and children at several university medical centers before assuming my current position at the NIH in 1981.

I am pleased to have the opportunity to tell you about problems that persist today with the use of therapeutic drugs in infants and children. It is ironic that major changes in this country's federal drug laws resulted from the use, or misuse, of drugs in children. The tragic deaths of 107 children from ingestion of elixir of sulfanilamide brought about the passage of the Federal Food, Drug, and Cosmetic Act of 1938, and later the terrible thalidomide malformations led to the 1962 Kefauver amendments to the Act.

Since many aspects of the dosage and biological activity of drugs are quite different in infants and children than in adults, separate testing must be conducted in the specific pediatric population before a drug can be approved for use with them. There are a number of medical and legal issues that make such testing difficult in infants and children; thus, for most drugs, it is not done. Indeed, fifty-five years after the enactment of the 1938 law, only about 20 percent of all drugs marketed in the United States have been tested and proven to be safe and effective for use in infants and children. The FDA has suggested that of the 80 drugs most frequently used to treat newborns and infants in U.S. hospitals, only five are labeled for use by children. This does not imply that 80 percent of our drugs are contraindicated, unsafe, or disapproved for use in infants and children. Rather it means that necessary testing has not been done to produce the data that would enable the Food and Drug Administration (FDA) to grant approval status for specific clinical indications and uses in pediatric populations.

Because neither the safety nor the efficacy of many of these marketed drugs has been demonstrated by actual clinical trial use in infants and children, the physician caring for the sick infant or child is faced with the dilemma of having to either avoid the use of the drug, that is, deprive children of the potential benefits of the therapeutic agents available to adults, or prescribe the drug despite the lack of FDA approval and, thus, certification of safety and efficacy. Consequently, the physician finds him- or herself in a quandary. Not providing the drug may deprive the young patient of a significant therapeutic agent. If, on the other hand, the drug is prescribed when it has not been adequately evaluated, an unanticipated adverse effect may occur and, of course, the physician may be subject to legal action.

The physician makes the decision to prescribe a therapeutic drug either on the basis of information contained in the labeling supplied by the manufacturer, or on the basis of data available in the medical literature. Uses in children and new uses for additional indications and different doses, will not be approved by the FDA until "substantial" evidence of safety

and efficacy for that indication and for that specific pediatric age group is submitted. "Substantial" has meant, under most circumstances, data obtained in a clinical trial. This regulatory process may take years, or may never occur, because there is less incentive to gather and submit data for new uses after a drug has been approved for marketing and the profit motive is no longer a factor. Labeling is intended neither to preclude physicians from using their best clinical judgment on behalf of their patients, nor to impose legal liability when physicians prescribe a drug for an indication that has not been FDA approved. It is a complex challenge to balance the interplay of clinical, ethical, and legal interests that arise in the use of drugs in infants and children.

Since virtually all of these concerns are eliminated or, at least, significantly lessened when drugs are tested and approved for use with pediatric populations, our Institute, in the last few months, has launched an initiative to facilitate and encourage the testing of drugs that will produce the clinical data necessary for FDA approval for their use in infants and children. Specifically, the NICHD has established a cooperative Network of Pediatric Pharmacology Research Units to serve as a resource for studies of drug action and disposition in pediatric populations. The six Units funded to comprise the Network are located at the University of Tennessee in Memphis; Children's Hospital in Columbus, Ohio; Children's Hospital of Michigan in Detroit; Louisiana State University in Shreveport; University of California at San Diego; and the Arkansas Children's Hospital in Little Rock.

Studies at these Units will be conducted by pediatric clinical pharmacologists, either with other investigators in the Network, in collaboration with pharmaceutical companies, or independently with other support. Data will be gathered on the safety and effectiveness of drugs specifically prescribed for newborns, infants and children through adolescence. This research will be immediately applicable to patient care, and will provide data that could lead to FDA approval for use in children.

While I am not an obstetrician, as a clinical pharmacologist I am aware that the problem of off-label use of drugs is even more severe in the case of pregnant women. To my knowledge, there are fewer than two dozen prescription drugs on the market today which have been appropriately evaluated and, therefore, labeled for use with pregnant women.

We expect that new drugs not yet on the market will be tested by the new Network, as well as drugs that are currently available. We believe that this new program will increase the number and variety of medications that are FDA-approved for use in children. It is our ultimate goal to ensure that all drugs prescribed for children have been evaluated and approved specifically for such usage.

Mr. Chairman, thank you, again, for the opportunity to appear before you today. I would be pleased to answer any questions you and the members of the Subcommittee may have.

**COMMENTARY****PROBLEMS OF DRUG TESTING IN CHILDREN IN THE  
UNITED STATES\***

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**INTRODUCTION**

The Food and Drug Administration (FDA) has statutory responsibility for ensuring the safety and effectiveness of marketed drugs for their intended uses and for ensuring that they are accurately and adequately labeled. This includes accurate dosage information and directions for their safe usage. The FDA requires that drugs must be tested for safety and efficacy before being approved

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for therapeutic use. This testing has to take into consideration the characteristics of the prospective population in which the drug will be employed. Under most circumstances the claims for efficacy and the demonstration of safety are provided to the FDA by data submitted by the pharmaceutical industry.

According to FDA regulations less than 25% of drugs marketed in the United States at the present time can be advertised as safe and effective for use in infants and children. This does not imply that the drugs are contraindicated, unsafe, or disapproved for use in infants and children; rather it signifies that sufficient data have not been provided to grant approval status for specific clinical indications and uses in the pediatric population. Since neither the safety nor the efficacy of many of these marketed drugs have been demonstrated by actual clinical trial for use in infants and children the physician caring for the sick infant and child is faced with the dilemma: either (1) avoid the use of the drug, that is, deprive children of the potential benefits of the therapeutic agents available to adults--the therapeutic orphan situation, or (2) prescribe the drug despite the lack of approval and thus certification by the FDA of safety and efficacy for use in children by the FDA. Thus, the physician finds himself in a quandary. If he does not use the drug, then he may deprive his young patient of a significant therapeutic entity. If, on the other hand, he uses the drug and an adverse effect occurs he may be subject to medical-legal action. The physician makes the decision for prescribing a therapeutic agent either on the basis of information contained in the labeling supplied by the manufacturer, or on the basis of data available in the medical literature. New uses (doses and indications) will not be approved by the FDA until "substantial" evidence of safety and efficacy for that indication and for that specific pediatric age group is submitted. "Substantial" has, under most circumstances, meant data obtained in a clinical trial. This regulatory process may take years, or may never occur, because there is less incentive to gather and submit data for new uses after a drug has been approved

for marketing and the profit motive is no longer operative. Labeling is intended neither to preclude the physician from using his best clinical judgment on behalf of his patients nor to impose medical-legal liability for failure to adhere to the indications that are contained in the label or package insert. These introductory remarks underscore the complex interplay between clinical, ethical, and legal precepts that bring to pediatric pharmacology, and the use of drugs in infants and children, a series of difficult problems that must be solved.

## HISTORICAL DEVELOPMENT OF FDA

Historically, the most recent significant changes in the FDA regulations were prompted by therapeutic tragedies affecting children. The FDA amendments were prompted by the elixir of sulfanilamide catastrophe in which many children died after receiving this liquid form of an antibacterial medication. A more recent change was embodied in the amendments of 1962, which declared that new drugs not only must be safe, as required in 1938, but they also must be shown to be effective prior to marketing and that the study of investigational drugs (prior to marketing) must be monitored carefully by the FDA. This second set of amendments, which are those under which we operate today, were the direct result of the thalidomide tragedy in which so many infants were malformed following intrauterine exposure to this very effective hypnotic sedative. In 1963, Dr. Harry Shirkey observed that "by an odd and unfortunate twist of fate, infants and children are becoming 'therapeutic or pharmaceutical orphans'." The term "therapeutic orphans" refers to the deprivation, actual or potential of sick children, of drugs that might be useful to them as a consequence of statements in the package inserts that such drugs have not been adequately tested in children and therefore lack dosage or other information relative to such usage. This situation is particularly an undesirable one for the sick child as well as for the

prescriber. Unfortunately it pertains to the majority of prescription drugs marketed today. Many factors have been incriminated in producing the therapeutic orphan situation. These include the lack of adequately trained pediatric clinical pharmacologists, inaction due to lack of profit motivation on the part of the drug manufacturer, and societal concerns for the risk of drug studies in general and for the ethicality of drug studies in children in particular. However, in my opinion, many of these factors are no longer applicable and pediatric clinical pharmacology today is a sophisticated discipline that is very capable of carrying out the studies necessary to assure the evaluation and subsequent usage of drugs for infants and children. The drug manufacturer, when spurred by the economic incentives of potential widespread usage of a new drug in the pediatric population, has encountered little difficulty in persuading well-trained investigators to study these drugs and with adequately well-controlled clinical trials to convince the FDA of substantial evidence of safety and efficacy.

How serious a problem is the "therapeutic orphan" situation? The firm data regarding this issue are difficult to come by. In 1975, Dr. John Wilson<sup>1</sup> in a pragmatic assessment found that 78% of prescription drugs carried a labeling statement against the use in infants and children or were silent in regard to such use because the drugs had been inadequately studied in infants and children to permit accurate dosage and appropriate indications for use. A decade later analyses of drugs that had been approved by the FDA show that 50% had pediatric studies undertaken under the sponsorship of the manufacturers<sup>2</sup>. This represented a significant improvement over the 22% that had not been subject to the orphaning clause in the previous decade. Currently Dr. Franz Rosa, FDA Epidemiologist, has surveyed prescription drugs available in 1988<sup>3</sup>. He has found that, with respect to use in infants, 50% have been evaluated in this population. Of this 50% half have been considered safe and efficacious and the remaining half have a caution or risk statement in the label. Fifty percent of the total have not

been evaluated and of these 60% have a label disclaimer and 40% have no statement on the label regarding usage in infants. This change in the "therapeutic orphan" situation represents a significant advance from the past but there certainly is room for improvement. As I understand it the current position of the FDA concerning pediatric drug studies is that they should be completed before marketing for (a) drugs which represent a major therapeutic advance and thus are likely to be used in children, and (b) drugs which do not represent any major advances but are likely to be used widely in children because of their applicability in the treatment of diseases that occur mainly in children. This has particular relevance to the newborn infant in view of the marked advances that have occurred recently in the management of low birth weight infants in the Intensive Care Nursery. Application of these guidelines should be flexible in order not to delay the approval and subsequent availability of significant new therapeutic entities for use in adult patients. For example, it is sufficient to indicate that studies are underway in children and not to wait until these studies are completed before giving approval for marketing for major therapeutic advances. In this case, the pediatric studies could be completed postmarketing (of the adult preparation). However, it is perfectly feasible to undertake postmarketing studies without premarketing for the initiation of pediatric studies for those drugs that represent only some advantage over available drugs and are likely to be used in children to a significant extent but not as widely as in (b) above.

Finally, because of limited resources, pediatric studies should not be required for drugs that appear to offer no advantage over those already available; these drugs instead should be marketed with the usual label disclaimers. In this particular case the manufacturer could, if he wishes, voluntarily perform the studies in children if he desires to use these drugs in the pediatric population, while marketing the drug for adults.



In the United States, the FDA has long been aware of the shortage of drugs adequately labeled for use in children (indicating the lack of data upon which to base substantial evidence of safety and efficacy). As a consequence, government, industry, and the academic community have attempted to develop solutions to this problem. A series of workshops and conferences have taken place over the past 15 years to indicate the concern with the problem and to highlight advances that are being made. The FDA also entered into a contract with the Committee on Drugs of the American Academy of Pediatrics to develop a solution to the problem. As a consequence, the Committee issued general guidelines for the evaluation of drugs to be approved for use during pregnancy and for treatment of infants and children (American Academy of Pediatrics, Committee on Drugs, 1974)<sup>4</sup>.

#### PEDIATRIC GUIDELINES

These general guidelines were adopted by the FDA and incorporated into its series of clinical guidelines for drug evaluation as publication 77-3041. These guidelines were updated and revised in 1979 by the Committee on Drugs<sup>5</sup>. The guidelines identify the research needs in terms of the special techniques that are required to study drugs adequately in young subjects. Emphasis is placed on the need to be aware of unexpected toxicities that may result from immature physiologic and metabolic mechanisms, operative because of the developmental status of the infant and child as distinct from those that are predictable from the drug's known pharmacologic properties (determined from studies in adults). Flexibility in research design is essential to permit modifications necessary to fit the nature of the drug, its intended use, and the age and developmental status of the pediatric patient. Guidelines for the clinical evaluation of specific classes of drugs have also been developed by the FDA.

The comprehensive guidelines concerning the clinical evaluation of drugs in infants and children emphasize that factors affecting both the safety and efficacy may be different in the pediatric population because of both quantitative and qualitative differences that arise from developmental physiologic changes. The development of adequate methods for the determination of the drug and its major metabolites in biologic fluids were emphasized with particular attention to the need for methods that might employ stable isotopes. Certainly considerable technological advance has been made in this general area. The variations in pharmacokinetics between the pediatric population and adults have been adequately publicized and have motivated extensive investigation both in Europe and in the United States<sup>6</sup>. These include variations in bioavailability that would have applicability particularly to oral formulations in view of the continually changing physiology of the gastrointestinal tract in young infants. Emphasis was also placed upon different types of drug interactions that might occur in the developing infant and child. Attempts should be made to correlate the pharmacokinetics with the pharmacodynamic responses to a particular drug in order to establish a concentration-response relationship. This is often difficult to accomplish because of the problem in quantifying drug effects particularly in infants and children. Where this information is available it can be used to monitor and optimize drug therapy.

The importance of experimental design both on practical and ethical considerations has repeatedly been stressed. In common with all research in human subjects, clinical research in children in particular involves use of a precious resource. It is imperative that investigators make maximum use of the information that can be obtained with as little inconvenience to the patient as possible. It is a general consensus that whenever possible investigators beginning new studies in children should thoroughly test their design and analytical techniques on animals and in adult subjects before initiating their pediatric

studies. There, of course, are times and indications for pathologic conditions which require treatment that are confined only to the pediatric population. While experimental design in the pediatric population may have to vary from the rigid protocol utilized in adults it must account for the adequate control of variables with appropriate statistical analysis. In addition, methods and appropriate validation must address not only the assessment of benefit but also the possibility of unusual adverse effects and a placebo response that may be different from that seen in adults.

Monitoring of clinical studies in infants and children should be intense and surveillance should be continuous. This, of course, does not differ from that required in the adult population but in infants and children there is an added element of unanticipated effect present that requires continuous surveillance.

#### AGE-DEPENDENT VARIABLES

In addition to general considerations, the guidelines adopted by the FDA also looked at specific age-dependent factors that might influence the demonstration and evaluation of safety and efficacy. In doing so, the pediatric population was divided into five (perhaps arbitrarily selected) age groups that were intended to warrant specific consideration. Underlying this approach was the concept that there were complex changes in the anatomy, physiology, biochemistry, and behavior from one stage of development to another over the time frame of growth from conception to adulthood. Each grouping attempted to divide the pediatric age group into stages that shared sufficient characteristics as to distinguish one stage from another. By introducing this concept, it was not suggested that each drug be tested in each age group; rather this was an attempt

to assure that the important biologic characteristics of each age group in which the drug would eventually be used under therapeutic circumstances be considered in evaluating its beneficial as well as undesirable effects. These age groups included the intrauterine period, encompassing conception to birth; the neonate (birth to 1 month); the infant-toddler (1 month to 2 years); the child (2 years to the onset of puberty); and the adolescent (onset of adolescence to adult life). Within each age group, certain characteristics of the biochemistry and physiology as well as behavior of that age have been identified to alert the investigator as to the specific ways in which investigation should be conducted, keeping in consideration the uniqueness of the subject at the various stages of development. Toxicities, in particular, vary from age to age because of developmental changes. I will not detail specific problems encountered by each age since these have been emphasized in previous reports. In general, the usual sequence of testing of new drug entities would first involve teenagers who can consent to participation, then successively younger children. Exceptions will occur when diseases are peculiar to one age group or another. The neonate must be approached with great care, since even studies in young children may not yield a reliable estimate of adverse effects that may be seen in the neonate. This caution must be given greater emphasis when considering the low-birth weight and very low-birth-weight infant. For studies of the fetus, the newborn infant treated as an inadvertent recipient by administration to the mother of a drug for a serious medical problem may be the first studies involving the fetus (neonate). There are many examples of this phenomenon in which detailed pharmacokinetic investigations from drugs administered in utero have yielded considerable insight into the ability of the newborn to handle the drug. Adverse effects in the fetus, of course, depend upon its stage of development when exposed to the drug given to the mother. It is simply not enough to look for anatomic birth defects but attention should also be paid to behavioral effects as well as effects that may be long term or delayed.



## ETHICAL CONSIDERATIONS

In 1974, the United States Congress established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research<sup>6</sup>. A part of their mission was to develop guidelines for the protection of certain categories of research subjects in various segments of the population with impaired ability to give truly informed consent. The report and recommendations of the Commission, with respect to research involving children, were issued in September 1977<sup>7,8</sup>. The Commission advised that "research involving children is important for the health and well-being of all children and can be conducted in an ethical manner" provided that certain conditions are met. These include the review and determination by an institutional ethical review board that (a) the research is scientifically sound and significant; (b) when appropriate, studies must be conducted first on animals and adult humans, then on older children prior to involving infants; (c) risks are minimized by using the safest methods, consistent and sound research design, and by using procedures performed for diagnostic or treatment purposes whenever feasible. Ethical aspects of drug investigation in infants and children were also published by the Committee on Drugs of the American Academy of Pediatrics. A new set of guidelines for the ethical conduct of studies to evaluate drugs in pediatric populations is being written by the Committee on Drugs of the American Academy of Pediatrics.

This commentary has attempted to provide background information concerning the problem of drug testing in children in the United States. The problem, however, is not unique to the United States but exists in other parts of the western world. Conferences and workshops in both the Federal Republic of Germany and Sweden have clearly identified the lack of randomized clinical trial drug data in infants and children as a serious issue. It is our hope that with the general recognition of the need and with the provision of adequate resources, the

requisite studies will be performed. This will eliminate the "therapeutic orphan" issue and benefit sick infants and children in need of rational drug therapy.

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Mr. WAXMAN. Thank you very much. I am glad you are here to respond to some of the questions that may come up.

I want to commend you all for your testimony and I want to ask some questions of you.

Mr. Perkins, the Clinton health care plan includes prescription drugs as a standard benefit for everyone that will be covered under the new health reform proposal, and Medicare, which will still be left in place, would have an additional benefit to cover prescription drugs.

Does the American Association of Retired Persons believe that coverage of prescription drugs is an essential component of any credible health care proposal?

Mr. PERKINS. Absolutely, Mr. Chairman. In fact, I would like to state that the National Legislative Council that met last week very definitely in its proposal said that we very definitely will insist that any proposal have universal coverage, prescription drugs for everyone, and long-term care for everyone along with cost containment. So that very definitely is a priority.

Mr. WAXMAN. Does anybody on this panel disagree with the idea that prescription drugs would be an essential component of any credible health care proposal?

[No response.]

Mr. WAXMAN. I don't see anybody disagreeing.

Mr. Perkins, unlike the Clinton plan, there are other proposals. Mr. Cooper has a proposal and Mr. Michel has a proposal. The Cooper proposal does not guarantee that prescription drugs will be covered for the persons on Medicare and it doesn't even guarantee that prescription drugs will be covered under other health care plans because it leaves to some other committee to decide what the standard benefit package would be.

Does the AARP believe the Cooper bill would provide an adequate level of health care coverage for persons on Medicare and for the rest of the population as it now stands?

Mr. PERKINS. We have great concerns with that. One of the reasons is just because of the lack of a defined benefit for prescription drugs. He does, I understand, allude to a situation whereby if 65-plus people join an alliance, there may be coverage, but that doesn't mean that it will be for all. We very definitely go on record as saying we want prescription drug coverage for all ages.

Mr. WAXMAN. Your attitude would be the same to the Michel bill and any other proposals that do not spell out the prescription drug benefit?

Mr. PERKINS. Absolutely. Yes, Mr. Chairman.

Mr. WAXMAN. Ms. Johnson, you refer to price controls in the President's health care plan. I want to point out to you that the plan doesn't contain price controls. Instead, it provides that the Secretary of Health and Human Services may choose not to purchase new drugs that are exorbitantly expensive and that there would be an advisory committee that would review the reasonableness of drug prices. As I understand the bill, that advisory committee doesn't even have the authority to compel companies to produce information justifying their price.

I would like to ask you whether you have any proposal to help us to restrain companies from charging \$50,000 or more for breakthrough drugs.

Ms. JOHNSON. I'm certainly not an expert on this. This is not my field. I feel that there has to be a middle ground here. You and I both know that a for-profit organization is not going to do something that isn't going to be profitable for them. We all have the same goals, I believe.

Mr. WAXMAN. I think it should be profitable. The question is, at what point is the profit so high that we just can't afford to pay that price? At what point can we say that they have gotten a very handsome return on the investment, but beyond that, because they are the only unique drug for any particular illness, they don't use that as a reason to charge an exorbitant amount of money?

What if I told you, for example, that many breakthrough drugs are developed by the National Institutes of Health, that the research is paid for by the American people? Do you believe that the government has any role in assuring the reasonableness of the price that a private drug company would be manufacturing and selling under those circumstances?

Ms. JOHNSON. I certainly think the government should have something to say about it, but it was my understanding that those drugs are developed in concert with assistance from the pharmaceutical associations. So I feel that it's a combination of two things. The government is working on it with the assistance of the pharmaceutical companies, and therefore you have to come up with a formula which is going to be positive for both. That's my feeling.

Mr. WAXMAN. I appreciate that.

Mr. Perry, I would like to ask you your views on this. Where we have these breakthrough drugs where the taxpayers are paying for a lot of the work, the basic research, and then the drug companies take it over, don't you think when the taxpayers have helped to produce the drug that we ought to have a say on what is a reasonable price that consumers would be asked to pay?

Mr. PERRY. I think since World War II, Mr. Chairman, we have really had an industrial policy in this country. We don't call it that. But in effect, we have encouraged academic government sponsored research, the National Institutes of Health and elsewhere, and we have had an environment which has encouraged private sector development companies to take that basic, fundamental research and apply it to the marketplace and bring new drugs on. It has made us the envy of the world.

Mr. WAXMAN. We are not the envy of the world, however, if the taxpayers pay for research, let's say for lupus, and then we develop a drug for lupus based on that research which a drug company takes over and then charges a price that the members of Ms. Johnson's organization couldn't possibly afford. Then it seems to me that something is wrong. If we are paying for research and development with taxpayers' funds, certainly in that circumstance the government should be able to insist that a reasonable price be charged for the drug, one that is affordable but one that is reasonable in that it gives a proper return to those people who made in the private side their own investments.



Mr. PERRY. I agree with you that we need to have mechanisms for bringing these issues out and making the prices affordable, but we are supporting that research at the National Institutes of Health not simply to make it easy for scientists but to produce real breakthroughs that will have an impact on people. It's the private sector by and large that brings that basic research down to where people can have access to it through the marketplace.

Similarly, whether it's high speed trains or new environmental technology, we invest in basic research and we hope that the private sector will bring these things to where people can have access to them. I doubt that we would be talking today about trying to restrain the prices of passenger tickets on a high speed train because we invested in the basic technology on the front end.

Mr. WAXMAN. We want the tickets on the train and the drugs for the people to be affordable by the users. Otherwise we have a system that only means that those who can pay the highest price get the benefit of what was a public investment that led to that new technology.

I'm going to recognize Mr. Wyden.

Mr. WYDEN. Thank you very much, Mr. Chairman.

Let me start with both ends of the age spectrum, the very young and the elderly.

Dr. Yaffe, where are the Nation's doctors today in terms of being able to get good information on the use of pharmaceuticals in children?

Mr. YAFFE. Information is available in the medical literature. Unfortunately, it's not available in the package insert, that is, the labeling which accompanies the drug, in prescription usage, because most of the drugs that are used in infants and children have never been evaluated in infants and children, that is, by FDA standards.

Mr. WYDEN. You might be interested in knowing that three kids have died recently in Oregon in deaths that are related to imipramine, one of the antidepressant drugs. You started writing about this problem, I think, 20 years ago. Three kids have died recently in Oregon. It is tied up now in litigation. I want to make it clear that these are allegations. I think it's a pretty good example that the information is not getting out.

With respect to you, Mr. Perry, I have appreciated the chance to work with you over the years as well. Would you agree that there is a great need for better information on the safety and effectiveness of drugs that are used by senior citizens?

Mr. PERRY. Most definitely, and better training of health professionals in knowing how to prescribe and monitor them as well.

Mr. WYDEN. The question, I guess, to both of you is, if both of you have said that there are some shortcomings in trying to get good objective data out, what would you think of the value of a proposal to give incentives to private drug and technology companies to bring this information to the government early on that shows how their product stacks up against the products that are already out there?

Dr. Yaffe.

Mr. YAFFE. I certainly agree with you that one needs to have the requisite studies done. That's the first thing. You need to study the

drug in the infant or child who needs the drug for the particular illness under question for which the drug would be used. Until you have that information there is nothing to disseminate.

Mr. WYDEN. Mr. Perry.

Mr. PERRY. I think it's a very interesting proposal. I believe that any rigorous outcomes research in this area, and we should have it, will probably underscore even more the cost-effectiveness of pharmaceutical drugs.

Mr. WYDEN. Let me ask you one other question, Mr. Perry. These are very costly trials, costly comparative trials. They are going to cost even more to get at special population groups. My sense is there are some drug companies in this country who both have deep pockets and are interested in this area who are going to be able to fund it, but there certainly is going to be lots of players out there in the pharmaceutical sector, like a small biotechnology company and other drug firms who, unless the government gives them specific incentives to bring this comparative data early on in the process of evaluating the drug, they are not going to be able to do it. Is that your sense?

Mr. PERRY. I can't speak for them, but I agree with you that incentives to encourage better outcomes research would probably point us in the right direction. It's an interesting proposal. I would like to study it.

Mr. WYDEN. One other question for you, Dr. Yaffe. I gather that you all have a new initiative which is somewhat in the same spirit of what I am talking about, a pediatric pharmacology research effort where you all are trying to get information out. My sense is that this is a very good effort and I commend you for it. But isn't there a much greater need for this information about how drugs affect young people than the government has money to provide either through your program or any other?

Mr. YAFFE. The answer to the question is yes. Let me just explain. We've established this network through competition in terms of research support. Our intent is to offer this infrastructure, if you will, for industry to utilize in studying drugs for use in infants and children.

Mr. WYDEN. One last point for Ms. Johnson and Ms. Meyers. We would be very interested in your thoughts on trying to develop this formula for addressing the drugs that are largely funded by the taxpayer. We have got to get a handle on it. Ms. Meyers, you have been before my subcommittee over the years. Half of the major breakthrough drugs, the cancer and the promising AIDS drugs, get developed when the taxpayer is doing the heavy lifting.

I want private sector firms to get a reward. It's a dangerous and risky kind of business, but in a lot of these instances I feel where there are taxpayer funds involved some of these drug companies are more Willy Loeman than Louis Pasteur, and we've got to figure out a way to have a formula that fairly allocates these costs.

I would be interested, maybe for the record, if your two organizations could give us some analysis of what kind of formula you think is appropriate where drugs get to market with a lot of support from the taxpayer.

Ms. MEYERS. I sense that the industry's concern about the breakthrough drug committee is along those lines in that if there is a

formula, will the government take every factor into equal consideration, that maybe the cost of manufacturing the drug or the cost of research and development will be weighted heavier than the general operating expenses that the company needs to carry on its normal business. I think that is something that this bill should be concerned about when talking about creating a formula that is fair to the companies and fair to the taxpayer.

Mr. WAXMAN. Thank you, Mr. Wyden.

Mr. Franks.

Mr. FRANKS. Thank you, Mr. Chairman.

Mr. Perry, how would research aimed at diseases that more greatly impact the elderly change if the Clinton administration's plan were to pass?

Mr. PERRY. We're concerned from two points of view. Dr. Lee referred to the current budget for the National Institutes of Health as if this was a great step forward. In fact, we can expect flat and, in many parts of the National Institutes of Health, declining research budgets over the next few years, in part because of the hard freeze on the budget, and if that is coupled with measures that drive biotechnology companies, pharmaceutical companies, diagnostic companies and others to veer away from the high risk, high cost investments in those drugs that are needed by the elderly population and the elderly population of the future, then we have sort of a pincer action that I believe could potentially leave us in the year 2020 with four times as many people over the age of 85 and with today's pain killers and palliatives. It's not good enough.

Mr. FRANKS. What advice would you offer us as committee members during the debate on the benefits of drugs for the elderly?

Mr. PERRY. To look to the future as well as to the present and realize that it needs to be a higher priority to do both the fundamental research and the development research to get to the next generation and the generation after that of highly more effective drugs aimed at chronic, disabling conditions of the elderly.

Mr. FRANKS. Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Franks.

This has been an excellent panel and I want to thank each of you for being here today.

Dr. Yaffe, you may have a prepared statement that you want to put in the record and we will be pleased to receive it. And there may be questions for members of the panel and we would request that if there are that you submit to us in writing any responses you wish to make to those questions.

Thank you very much.

For our third panel, I would like to call forward Lewis Engman, President of the Generic Pharmaceutical Industry Association, Gerald Mossinghoff, President of the Pharmaceutical Manufacturers Association, Dr. Charles Sanders, Chairman and CEO of Glaxo, Inc., G. Kirk Raab, President and CEO of Genentech, Inc., and Dr. Roy Vagelos, Chairman and CEO of Merck and Company, Inc.

We are pleased to welcome you to our hearing today. Your prepared statements will be in the record in full. What we would like to ask each of you to do is to limit the oral presentation to 5 minutes.



Mr. Mossinghoff, why don't we start with you, and we'll just go straight down the table.

**STATEMENTS OF GERALD J. MOSSINGHOFF, PRESIDENT, PHARMACEUTICAL MANUFACTURERS ASSOCIATION; P. ROY VAGELOS, CHAIRMAN, MERCK & CO.; KIRK RAAB, PRESIDENT, GENENTECH, INC., ON BEHALF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION; CHARLES A. SANDERS, CHAIRMAN AND CEO, GLAXO INC.; AND LEWIS A. ENGMAN, PRESIDENT, GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION**

Mr. MOSSINGHOFF. Mr. Chairman, in the interest of time, I will ask that my prepared statement be put in the record and I would defer my time to Dr. Vagelos and Dr. Sanders.

Mr. WAXMAN. Very good. Your prepared statement will be in the record in full.

[Testimony resumes on p. 650.]

[The prepared statement of Mr. Mossinghoff follows:]



# Statement

**Pharmaceutical  
Manufacturers  
Association**

GERALD J. MOSSINGHOFF  
PRESIDENT  
PHARMACEUTICAL MANUFACTURERS ASSOCIATION

BEFORE THE

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT  
OF THE  
COMMITTEE ON ENERGY AND COMMERCE

UNITED STATES HOUSE OF REPRESENTATIVES

FEBRUARY 8, 1994

Mr. Chairman and Members of the Subcommittee:

I am Gerald J. Mossinghoff, President of the Pharmaceutical Manufacturers Association. PMA represents more than 100 research-based pharmaceutical companies -- including more than 40 of the country's leading biotechnology companies -- that discover, develop and produce most of the prescription drugs used in the United States and a substantial portion of the medicines used abroad. I appreciate the opportunity to appear today at this important hearing on the role of the pharmaceutical industry in healthcare reform.

Our companies support President Clinton's goal of assuring healthcare security for all Americans without sacrificing quality of care. To accomplish this goal, comprehensive healthcare reform is needed. Total healthcare costs are rising too fast. And too many people lack coverage for necessary medical care, including prescription drugs. These problems must be addressed.

The Administration is to be commended for proposing a comprehensive healthcare-reform plan that addresses all elements of an extremely complex healthcare system. We support strengthening consumer choice among competing private plans, rather than mandating a single-Government payer. We support providing comprehensive benefits, including prescription drugs, for all Americans. We support continuous coverage regardless of illness. We support greater emphasis on prevention and medical outcomes. And we support strong safeguards to ensure quality care. We also are pleased that the Administration has indicated that it will remain flexible and open to constructive suggestions on ways to improve its proposal. We believe that there must be greater reliance on the free competitive market in a reformed healthcare system.

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As Congress works to achieve comprehensive healthcare reform, we believe three overriding principles must be kept in mind.

(1) ALL AMERICANS SHOULD HAVE PRESCRIPTION-DRUG COVERAGE

o The first principle is that coverage for prescription drugs must be provided to all Americans just like coverage for other medical treatments. Drugs not only prevent disease and save lives -- they save money. They keep patients out of hospitals, out of nursing homes, out of emergency rooms, out of doctors' offices, out of surgery -- and on the job. And to ensure that there is no disincentive to the use of drugs, we urge that they be included in a common deductible with other medical services. We take this position with the full knowledge that expanded drug coverage, as defined in the Administration's proposal, would result in a substantial net loss of revenues for pharmaceutical companies, as discussed later in more detail.

Under the Administration's plan, millions of people who now lack drug insurance -- including older Americans -- would be covered for the first time. Because so many people currently lack such coverage, the cost of medicines is a particular burden to patients compared to the cost of other, more expensive healthcare services that are normally covered by insurance. In 1991, the most recent year for which the Government has published actual healthcare expenditures, the country spent \$289 billion on hospital costs -- about eight times what was spent on pharmaceuticals. Yet Americans paid twice as much on drugs out of their own pockets -- \$20 billion -- as they spent out-of-pocket on hospital bills -- \$10 billion -- as shown in Figure 1.

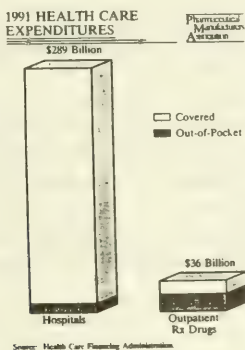


Figure 1.

Drugs are not only the most cost-effective form of medical treatment -- they represent a small share of national healthcare expenditures. Outpatient prescription drugs as a percentage of national healthcare expenditures have declined from 8.9 percent in 1965 to just 4.8 percent in 1991. While healthcare costs have increased rapidly, the share of Gross Domestic Product spent on prescription drugs has remained relatively constant for the past three decades -- at just over one-half of 1 percent, as shown in Figure 2.

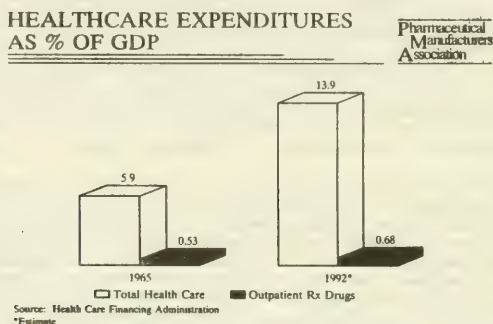


Figure 2.

(2) COMPETITION CAN AND MUST BE RELIED ON TO CONTROL COSTS

o The second principle is that market competition can and must be relied on to control costs, without Federal Government price regulation or other unnecessary and anti-competitive Government intrusion in the market.

Competition is working in today's pharmaceutical market. Radical changes have occurred and are continuing to occur in that market -- and these changes already are restraining drug prices for existing and new drugs. A number of articles have discussed the new pharmaceutical marketplace, including reports by David S. Hilzenrath in The Washington Post on January 25, 1994, James K. Glassman in The Washington Post on January 7, 1994, and Ruth Shalit in The New Republic on December 13, 1993. The new environment was succinctly described in these terms in the May 3, 1993 edition of Fortune magazine:

"No matter what happens in Washington market forces are already bringing the lower drug prices that politicians and consumers seek. Two factors have converged to change the prognosis for the industry: The onset of managed care has

altered demand, and a profusion of low-cost alternatives to high-priced drugs has increased supply."

According to an April 1993 study by The Boston Consulting Group (BCG), "Managed care grew explosively in the 1980s.... Managed care organizations use a number of tools to reduce drug budgets, including formularies, drug utilization review, generic substitution, aggressive discount negotiations, and demands for demonstration of the economic value of the products. Their success, particularly in more active therapeutic areas where several competitive compounds are available (e.g., H2 antagonists, ACE inhibitors), has put intense pressure on the pharmaceutical industry to deliver high value for low cost."

Unlike European Governments, the U.S. Government decided to rely on generic competition to control prescription-drug costs with the enactment of the Waxman/Hatch Drug Price Competition and Patent Term Restoration Act of 1984. The law accelerated the approval of generic products by the Food and Drug Administration. As a result, the generic share of the prescription-drug market doubled from 15 percent to 30 percent during 1983-1989. This year, more than 50 percent of all new prescriptions in the U.S. are expected to be filled by generics. Continued strong growth in the generic industry is anticipated as more than 200 drugs with \$22 billion in 1991 sales will come off patent during the 1990s.

In addition, 18 PMA companies, representing about two-thirds of the U.S. market for prescription drugs, individually and voluntarily are keeping their average price increases at or below the inflation rate.

The major market changes -- spurred by the growth of managed-care programs, generic competition and concerns about possible price regulation -- have had an enormous impact on pharmaceutical companies. Fourteen leading companies have announced job cuts of more than 30,000 employees in just the past 14 months. According to an October 21, 1993 report by Price Waterhouse, "The 13 pharmaceutical companies tracked by Standard and Poor's lost \$90 billion in market value over the 18-month period ending June 30, 1993." And a January 18 article in The Wall Street Journal reported that company profits are taking a big hit:

"Under pressure to discount prescription drug prices, the pharmaceutical industry is expected to post the slimmest quarterly profit gain in more than a decade. Securities analysts predicted fourth-quarter earnings will rise on average 3% to 6%, compared to 15% to 20% increases generated by major drug makers from the mid-1980s through 1992."

As a result of these powerful market forces and

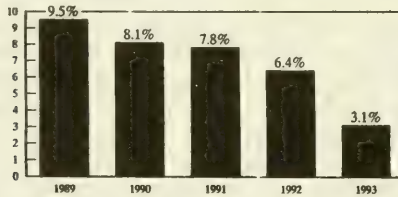


voluntary company actions, price increases for existing and new drugs are dramatically slowing during the 1990s. The rate of increase in the Producer Price Index for pharmaceuticals dropped to its lowest level in almost 20 years in 1993, declining by more than half from 1992's rate of 6.4 percent to 3.1 percent. The 1993 rate -- the fourth straight annual decline -- was less than a third of the 9.5 percent rate recorded in 1989, as shown in Figure 3.

### PRODUCER PRICE INDEX FOR PHARMACEUTICALS

Pharmaceutical  
Manufacturers  
Association

#### Percent Increase



Source: U.S. Department of Labor, Bureau of Labor Statistics, 1994

Figure 3.

The prices for new products also show a moderating trend. Prices for new products approved and launched during 1991-1992 were on average 14 percent lower than the leading product in the same therapeutic category, according to the BCG study.

In testifying on November 16 before the Senate Special Committee on Aging, Judith L. Wagner, Ph.D., Senior Associate of the Health Program at the Office of Technology Assessment (OTA), concluded that growing market competition in the pharmaceutical industry will continue to restrain drug-price increases:

"Together, these developments have created a new market place in which employers and insurers have both strong incentives and the power to contain the costs of prescription drugs by forcing drug companies to compete more vigorously on the basis of price....Thus, over the next few years, growing price competition can be expected to provide a strong moderating influence on the rise in prescription drug expenditures."

#### (3) THE DISCOVERY OF NEW CURES MUST BE ENCOURAGED

o The third principle is that the discovery of new cures must be encouraged as the best way to maintain and improve the

quality of care for patients and to contain healthcare costs, now and for future generations.

Unlike many other U.S. industries, the research-based pharmaceutical industry continues to increase its investment in research and development -- although the rate of increase is slowing. PMA's annual year-end survey in December showed that pharmaceutical companies are expected to invest \$13.8 billion in research and development in 1994, up from \$12.6 billion last year as shown in Figure 4.

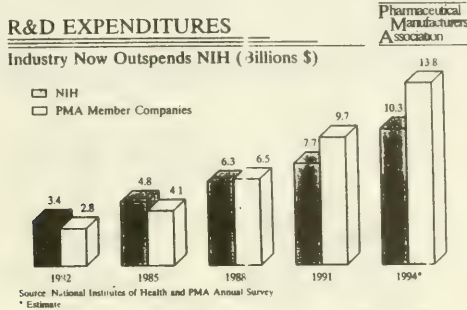


Figure 4.

But for the second straight year, the industry's increase in R&D investment is expected to be significantly less than it was on average between 1980 and 1992. In 1993, the industry's rate of increase in R&D spending was 10.2 percent. This year, it is anticipated that the rate will drop to 9.3 percent -- the smallest increase since 1972. The 1993 and 1994 rates compare to average annual increases of more than 16 percent from 1980 through 1992. The industry had been doubling its R&D expenditures every five years since 1970 -- and still will invest substantially more than the entire Federal Government will spend on all biomedical research.

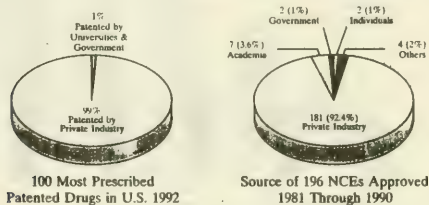
PMA's survey further shows that 20 major PMA companies are projecting a decline in their R&D growth in 1994 when compared to 1993. When research and development spending is adjusted for inflation using the NIH Biomedical Research and Development Price Index, six of those companies actually expect to invest less in real terms in R&D this year than they did last year. Nevertheless, pharmaceutical companies expect to invest a higher percentage of sales in R&D in 1994 than they did last year --

18.8 percent compared to 18.3 percent. This is more than four times the average rate for all U.S. industries engaged in R&D.

The research-based pharmaceutical industry -- not the Federal Government, as many people believe -- is the source of almost all new drugs discovered and developed in the United States. As shown in Figure 5, private industry was the source of more than 92 percent of the new chemical entities approved in the U.S. during 1981-1990 -- while the Government accounted for just 1 percent. And of the 100 most prescribed patented drugs in the U.S. in 1992, 99 were patented by private industry.

### SOURCES OF NEW DRUGS

Pharmaceutical  
Manufacturers  
Association



Source: PMA Survey; Center for the Study of Drug Development, Tufts University (1991)

Figure 5.

In the Briefing Book on its healthcare-reform proposal sent to Members of Congress on October 13, the Administration discussed the value of biomedical research generally in terms that eloquently describe the value of pharmaceutical R&D: "The history of American medicine is in large part the story of tremendous advances in medical research that has saved lives, improved the quality of care and helped reduce health care costs. Advancing research and technology increases the potential for more effective, low-cost treatments. Small investments in research have historically paid billion dollar dividends in decreased costs and restoration of productivity."

Just as medicines have conquered diseases of the past, including tuberculosis, polio, syphilis and diphtheria, the industry's new therapies will succeed in combatting the diseases of the present -- if the incentives for pharmaceutical innovation are preserved. Pharmaceutical breakthroughs, including those from biotechnology, provide the best hope that new cures and treatments will be developed. The rise of biotechnology follows earlier scientific advances that also led to better understanding

of disease and ultimately more effective medicines. Pharmaceutical innovation has followed a pattern in the treatment of disease -- from relief of symptoms, to control of disease mechanisms and finally to cure or prevention. Products now in the pipeline could provide more cures and better controls for many of today's most intractable and costly diseases.

For example, the industry has almost 300 medicines in human clinical trials or awaiting approval at the Food and Drug Administration for just eight diseases that afflict older Americans. These eight diseases alone -- osteoporosis, diabetes, stroke, depression, arthritis, Alzheimer's, cancer and cardiovascular disease -- cost the United States more than \$430 billion a year, as shown in Figure 6. A cure for just one of these diseases would produce enormous benefits by improving patient health and cutting healthcare costs.

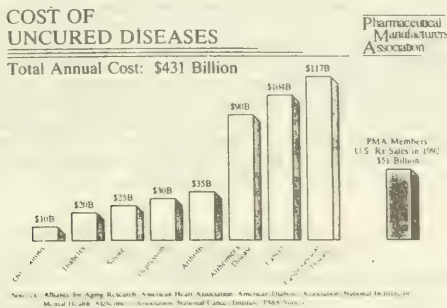


Figure 6.

#### Loss of Revenues

The three principles just discussed, applied to the Administration's healthcare-reform bill, raise several serious concerns. One major concern is the enormous financial impact the bill would have on pharmaceutical companies.

The Administration's bill would result in a substantial net loss of revenue for research-based pharmaceutical companies. According to Donald Muse, Ph.D., a former senior analyst at the Congressional Budget Office and now President of the Policy Research Group, a healthcare consulting firm, the brandname pharmaceutical industry would lose from 5.9 percent to 11.2 percent of sales under the Administration's proposal. On the other hand, generic manufacturers would gain between 33 percent



and 51.4 percent in revenues. In a separate analysis released last December, Lewin-VHI, Inc., a healthcare consulting firm, estimated that the average research-based pharmaceutical company likely would lose 6.7 percent of revenues under the Administration's plan.

For brandname firms, the gains from increased use of prescription drugs and the eventual elimination of Medicaid rebates would be more than offset by other provisions in the Administration's plan. These offsetting provisions are primarily the Medicare rebates and the incentives to encourage generic prescribing.

#### New Laws Already Cost \$14.5 Billion

The Administration's bill would be just the latest in a series of Federal laws that have had a profound adverse financial impact on research-based pharmaceutical companies. In its October 1993 study, Price Waterhouse calculated the combined impact on pharmaceutical companies of: (1) Medicaid rebates on prescription drugs mandated by the Omnibus Budget Reconciliation Act (OBRA) of 1990, (2) rebates to the Veterans Administration and the Defense Department required by the Veterans Health Care Act of 1992, (3) user fees specified by the Prescription Drug User Fee Act of 1992, and (4) the revenue-raising provisions provided under OBRA 1993. The financial impact of this legislation is shown in the chart below:

**Economic Impact of Recent Legislation on the  
Pharmaceutical Industry, FY 1994-1998**  
[Billions of dollars]

Provision	1994	1995	1996	1997	1998	1994-98
1. Revenue-raising provisions of OBRA 1993	\$0.484	\$0.724	\$0.726	\$0.697	\$0.667	\$3.298
2. Medicaid rebates (OBRA 1990)	\$1.547	\$1.752	\$2.018	\$2.373	\$2.518	\$10.208
3. VA and DoD price discounts (Veteran's Health Care Act of 1992)	\$0.105	\$0.109	\$0.114	\$0.120	\$0.125	\$0.573
4. Prescription drug user fee (Prescription Drug User Fee Act of 1992)	\$0.054	\$0.075	\$0.078	\$0.084	\$0.090	\$0.381
Total	\$2.190	\$2.660	\$2.936	\$3.274	\$3.400	\$14.460

Source: Price Waterhouse.

The costs to pharmaceutical companies as a result of the four new Federal laws will total \$14.5 billion from 1994 through 1998. The average annual cost of the legislation -- \$2.9 billion a year -- represents almost 25 percent of the industry's total investment in research and development in 1993.

### Huge Increase In Tax Burden Rate

If the four new Federal laws mentioned above had been in effect in 1992, Price Waterhouse has calculated, the pharmaceutical industry would have faced a tax burden rate of 41.4 percent of pre-tax income. The "burden rate" includes Medicaid rebates, veterans' discounts, and FDA user fees, plus Federal income taxes. The industry's actual tax rate in 1992 was 31.2 percent. Price Waterhouse also calculated the additional impact of the Administration's proposed Medicare rebate as if it had been in effect in 1992:

"If the Administration's Health Security Act were enacted, the combined tax burden rate would initially rise to 55.3 percent of pharmaceutical industry income due to the proposed Medicare rebate, and then drop down to 44.2 percent in 1998 when Medicaid rebates are scheduled to terminate under the Administration's plan."

At either 44.2 percent without the Medicaid-rebate tax or 55.3 percent with it, the enormous additional financial burden of the proposed Medicare rebate on pharmaceutical companies inevitably would siphon away funds available for the research and development of new life-saving, cost-effective medicines. The financial impact of any healthcare-reform plan on research-based pharmaceutical companies must be fully recognized -- particularly in view of the substantial costs already imposed by the four new Federal laws.

Several of the specific provisions in the Administration's healthcare-reform bill -- including the provision for a Medicare-rebate tax -- would adversely affect patients, the prospects for saving healthcare dollars and one of America's most internationally competitive high-technology industries. These provisions would undermine the incentives for pharmaceutical research and development -- the best hope for improving patient health while reducing healthcare expenditures.

### Medicare-Rebate Tax

As noted, pharmaceutical manufacturers would be required to pay billions of dollars in Medicare-rebate taxes to the Federal Government. Such a rebate would reduce revenues to pharmaceutical companies in precisely the same manner as an excise tax. The proposed Medicare-rebate tax would apply to a third of the total U.S. pharmaceutical market. As discussed, a Medicare-rebate tax would raise pharmaceutical companies' tax burden rate to 44.2 percent or 55.3 percent, depending on whether the Medicaid-rebate tax is terminated in 1998 as proposed by the Administration. Either way, substantially less money would be available to fund the industry's investment in research and development, slowing the development of new cures.

In addition, a Medicare-rebate tax would lead to the creation of yet another Government bureaucracy to track Medicare drug usage and attempt to document, audit and collect rebates.

#### Government Blacklisting Of New Drugs

The Administration proposes to empower the Secretary of Health and Human Services (HHS) to blacklist a new drug -- i.e., deny coverage for Medicare patients -- if the Secretary determines the drug is "excessively priced." This would give the Federal Government broad power to regulate pharmaceutical prices. We fear that such power would be used principally to address budgetary pressures, not the medical needs of patients. It could very well stifle the development of new life-saving, cost-effective medicines by all pharmaceutical companies, particularly biotechnology companies -- most of which do not yet have products on the market and depend on investors as their only source of research funding.

What company would be willing to invest the necessary time (about 12 years) and money (an average of \$359 million) to discover and develop a new drug with the prospect that Federal Government regulators might blacklist the drug because they feel its price is "excessive"? And those new medicines that are developed and are blacklisted would be available to all patients except those elderly who could not afford to purchase the drugs on their own.

#### Public Utility-type Price Commission

A public utility-type Price Commission -- the so-called "Advisory Council on Breakthrough Drugs" -- would have the power to "examine the reasonableness of launch prices of new drugs that represent a breakthrough or significant advance over existing therapies." This would not only be unwise and unnecessary, it also would be virtually impossible to implement, as was pointed out by Dr. Wagner of the OTA in her testimony on November 16: "It is extremely difficult, if not impossible, to know what the 'right' price for a breakthrough drug is. Every criterion for evaluating the entry price of a new drug is problematic."

The Advisory Council would not be the only one charged with monitoring drug prices. The HHS Secretary also would be required to monitor price increases in each sector of the healthcare system and report the findings periodically to the President. There is no need or reason for an Advisory Council to duplicate a function to be performed by the Secretary -- especially when the Council would concentrate solely on just one segment of the healthcare system. Further, while the Council would only have the authority to publicize prices, a structure would be in place whose powers could easily be expanded to include the power to regulate the price of drugs. The Council would thus be the first

major step to reducing the industry to a public utility, chilling precisely the kind of research the Government says it wants to encourage -- high-risk R&D against the most intractable diseases. The competitive marketplace -- not the Federal Government -- should determine the value of new medicines to patients.

#### Prior Approval

The HHS Secretary would be empowered to require physicians or pharmacists to obtain prior Federal Government approval before prescribing or dispensing a medicine under Medicare if the Secretary believes the drug is "not cost effective."

Two of the Administration's major goals in healthcare reform are to achieve simplicity and reduce costs. In an address to Congress last September, the President promised to "simplify government rules and regulations so that a doctor doesn't have to check with a bureaucrat in an office thousands of miles away before ordering a simple blood test." Yet the Administration proposes to establish just such a system for Medicare patients. Requiring prior approval before these patients could receive certain drugs would create a huge bureaucratic roadblock -- with doctors from all around the country jamming Federal switchboards trying to get through to Federal operators so their patients could receive the medicines they need.

Prior-approval requirements also would subject elderly and disabled Medicare patients to unwarranted Federal bureaucratic intrusion and limit the access of these patients to needed medicines. Under the Medicaid program, which now permits states to impose prior-approval restrictions, patients are denied timely access to some medicines, but there is no evidence that this reduces total healthcare costs. Indeed, prior-approval systems -- because they deny immediate access to all medicines -- can raise total costs by increasing the use of more expensive treatments such as hospitalization and physician visits.

A patient's physician should decide which medicine a patient receives -- not a committee of Federal bureaucrats that has no knowledge of the patient's unique condition and medical history.

#### Medical Liability

Disappointingly, the Administration would attempt to cover doctors, nurses and hospitals in medical-liability reform, but not the manufacturers or suppliers of medical devices and medicines. Malpractice reform without product-liability reform would shift the cost of litigation and liability from physicians and hospitals to manufacturers and suppliers -- at the expense of healthcare innovation.



### Anti-Discount Requirement

Pharmaceutical manufacturers, as a condition of participating in Medicare and Medicaid, would have to agree to severe limitations on their right to offer discounts to selected purchasers. Such an anti-competitive prohibition would be inconsistent with the Administration's overall attempt to stimulate competitive market forces. Price competition is central to any market-based effort to restrain healthcare costs. The ability of a healthcare plan to offer higher quality healthcare within a fixed premium would depend in part on the plan's ability to negotiate with product suppliers as well as service providers.

In analysing the Administration's plan, Merrill Lynch, in an October 7, 1993 analysis, stated, "In total, the [Administration's] proposals, if adopted, would place the drug industry into a quasi-public utility structure, in our judgment."

### Price Regulation Of Drugs Would Slow Innovation

Price regulation of pharmaceuticals would be particularly harmful. Studies show that price regulation of pharmaceuticals stifles innovation -- which harms patients and increases overall healthcare costs. The U.S. International Trade Commission, in a 1991 study of the pharmaceutical industry, stated, "The enactment of cost-containment programs, price controls, or both, on a national level often results in decreased levels of R&D spending in that these programs reduce revenues that can be reinvested in R&D programs. Several countries that have implemented such programs have seen their pharmaceutical industries weaken or shift outside their borders."

Regulation of drug prices would be especially harmful because it would bias research towards low-risk, low-benefit new products. Heinz Redwood, an industry analyst, wrote in a recent study, "Price regulation causes drug industry decisionmakers to shorten their time horizons and to reduce the scientific risk inherent in their research projects. The search for relatively quick, predictable results safeguards a satisfactory, if uninspiring, financial performance. In the long run, such policies produce an industrial formula that seeks to imitate rather than innovate."

An editorial in the April 2, 1993 edition of Science magazine summed up the impact of drug price regulation in this way: "The major casualties of excessive price pressure on drugs would be the small biotechnology companies, the rate of development of new drugs to relieve human suffering, and global leadership of the United States in creating new pharmaceuticals."

World Leader

For many years, the pharmaceutical industry's success in developing new and better medicines has made it one of the country's most innovative and internationally competitive industries. The industry has a good chance to remain innovative and competitive -- if the incentives for pharmaceutical innovation are preserved.

In its 1991 study of the industry, the ITC reported that U.S. firms accounted for nearly two-thirds of the new drugs introduced in the world market during 1940-1988. In his recent study, Heinz Redwood stated, "The American industry has a clear and outstanding lead in discovering and developing major, medically innovative, globally competitive, and therapeutically accepted new drugs... Perhaps the most important finding is that the American lead includes all but one of the therapeutic classes." The General Accounting Office, in a September 1992 study, concluded that the pharmaceutical industry maintained its competitive position and strong international leadership during the 1980s, while most other high-technology industries experienced some decline in their position. A report in the March 9, 1992 edition of Fortune magazine placed the pharmaceutical industry at the very top of the list of the country's most internationally competitive industries.

In conclusion, we believe the three principles outlined earlier in this statement -- coverage, competition and cures -- are fully consistent with the six goals specified by President Clinton for his healthcare-reform plan. Our industry firmly believes we can contribute significantly in helping to meet these worthy goals. We look forward to working with this Subcommittee in your efforts to achieve healthcare reform in a way that will accommodate our major concerns.

Mr. Chairman, that concludes my prepared Statement. I will be pleased to answer any questions that you or other Members of the Subcommittee may have.

Mr. WAXMAN. Dr. Vagelos.

### STATEMENT OF P. ROY VAGELOS

Mr. VAGELOS. Mr. Chairman and members of the subcommittee, my name is Roy Vagelos. I am Chairman and Chief Executive Officer of Merck. I am foremost a physician and biomedical scientist. Today I am going to contrast how research decisions have been made at Merck in the past with how they likely would be made under the Health Security Act.

In the United States there are about 10 million men with benign enlargement of the prostate. Every year some 400,000 undergo prostate surgery at a cost of \$3 billion.

Merck first started researching prostate disease in the 1960's. However, in 1975 a new development was reported: An enzyme deficiency in certain families caused even the oldest males to have very small, immature prostates. As head of Merck research at that time, I faced a major decision: Should I expand our program based on this important new information?

Despite the fact that this project had a high risk of failure, I approved it. In 1992, after 16 years, the expenditure of millions of dollars and clinical trials, including 1,600 men, we brought to market Proscar, the first therapy that can shrink enlarged prostate glands and improve the symptoms of this disease. Proscar is now the subject of a massive study involving 18,000 older men to determine if this drug can also prevent the development of prostate cancer.

The story of Proscar is not unique. Merck often has been presented with long-term, high risk scientific opportunities and has pursued them. We are spending over \$1.2 billion annually on research and development. Our 5,000 scientists and researchers have projects in such critical areas as osteoporosis, Alzheimer's disease and cancer. Our AIDS project, which I approved in 1986, is the largest and most costly in the history of our company. To date we have invested hundred of millions of dollars.

But now let me go through these research decisions again, with one change. It is now 1996 and the Health Security Act is law.

The first difference I notice is that an amount equal to about one quarter of our company's total annual research budget is being paid to HHS for Medicare rebates.

The second thing I notice is that in order to determine the reasonableness of the price of a breakthrough drug a National Advisory Committee reviews how this drug is priced in 21 countries. Some of these countries have low standards of living; others have price control systems that favor their own domestic manufacturers. Yet our prices will be judged based on those foreign prices regardless of other important factors such as the impact of currency exchange rates or the need to support innovation.

The third thing I notice is that mandatory insurance premium caps have forced private purchasers to ratchet down even further on the prices and use of our drugs.

Fourth, HHS has authority to exclude new drugs from Medicare coverage.

Finally, I'm aware of the cumulative impact on the pharmaceutical industry from previous government actions: mandatory dis-

counts, Medicaid rebates, FDA user fees, and OBRA 93, which totals some \$14.5 billion in costs and lost revenues over 5 years.

In short, my ability to fund R&D has been seriously diminished. In this event, I would most likely cut out some high risk projects. That would not be a good development for tens of millions of people who suffer from serious diseases and who look to companies like ours to invest in funding new cures and treatment.

Some will say this is not a problem because the NIH really does the research. This was addressed earlier. Speaking as one who has worked in both the NIH and the pharmaceutical industry, I can vouch for the critically important contributions of NIH in the area of basic research. But there is no way that the NIH can or should replace the applied research that is done by private industry.

In closing, Merck believes that there are significant health care reforms that Congress should pass this year and we want to play a constructive role in helping you do that. At the same time, we must not undermine our ability to research and develop new medicines which, in the final analysis, are the best hope for conquering disease and lowering health care costs.

Thank you. I would be happy to answer questions later.

Mr. WAXMAN. Thank you very much, Dr. Vagelos.

[Testimony resumes on p. 666.]

[The prepared statement of Mr. Vagelos follows:]



**STATEMENT OF P. ROY VAGELOS, M.D.  
CHAIRMAN AND CHIEF EXECUTIVE OFFICER  
MERCK & CO., INC.  
HOUSE ENERGY & COMMERCE SUBCOMMITTEE  
ON HEALTH AND THE ENVIRONMENT  
FEBRUARY 8, 1994**

Good morning, Mr. Chairman and members of the Committee. My name is Roy Vagelos. I am Chairman and Chief Executive Officer of Merck & Co., Inc., the world's largest research-intensive pharmaceutical products company. Merck discovers, develops and markets pharmaceutical products in over 150 countries and territories. We have 8 major research facilities worldwide, and employ over 5,000 people in research.

For more than a century, Merck has been committed to a tradition of pharmaceutical innovation. Researching the mechanisms of disease and discovering important medicines are what the Company does best. Towards this goal we have dedicated billions of dollars to mesh the best scientific minds with the most advanced technology and research facilities. In 1993, Merck invested \$1.2 billion in research, almost \$5 million every workday of the week. This spending is more than double what we invested just six years ago in 1987.

Although my primary responsibility at Merck is to oversee and coordinate our global business operations, I am foremost a medical researcher and physician. As a physician, I have practiced and followed the Hippocratic Oath which admonishes, in essence "above all else, do no harm." As Congress wheels America's health care system in for reconstructive surgery, I would urge you likewise to take the oath to "do no harm."

**FIX WHAT AILS AMERICA**

To be sure, our nation's health care system manifests the troubling symptoms of insurance coverage gaps, paperwork blizzards, rising costs and even lack of services for some of our

citizens. Complacency is unacceptable; reform must come. But in our zeal to fix the system we must be careful to address what truly ails America--and protect what makes us strong.

Merck believes that this country's medical innovation--new technologies and new medicines--is one of our strongest assets and it is the envy of the world. Our National Institutes of Health (NIH) is second to none. Our universities are basic research powerhouses. And the U.S. pharmaceutical industry--which leads the world in applied research--brought to the world market about half of the important new drugs introduced over the past two decades.

*It is critical that innovation be woven tightly into the fabric of America's reform legislation* because new and better drugs are the best chance for more effective and lower-cost solutions to disease.

For example, there are more than 900,000 hospitalizations each year in the U.S. for congestive heart failure, at an average cost of \$10,500 per stay. In clinical studies, Merck's VASOTEC, which costs less than a dollar per day, reduced the number of hospitalizations by 30 percent in patients with symptomatic heart failure and left ventricular dysfunction -- which is a weakening of the heart's main pumping chamber. We estimate that if this drug could be made available to all heart failure patients, it could save \$1.4 billion per year.

To flourish, innovation requires the economic incentives of a free market environment. In fact, Mr. Chairman, Merck believes that it is *only* in a market-based system that America can retain adequate incentives for both forward-looking pharmaceutical research and development and competitively priced drugs. I will provide examples that the marketplace is already working and that more regulation is not needed.

To be sure, the need to retain incentives is more important today than it ever was. The diseases of earlier decades, caused predominately by external agents such as toxins and bacteria, were easy research targets for prevention compared with the diseases that have more complex etiologies. The degenerative diseases of the 1990s--heart disease, cancer, dementia, emphysema, arthritis, not to mention AIDS--will test our skill at molecular and chemical engineering and require *future long-term* commitments to research and development of enormous magnitude. *These commitments will only be made if an adequate return can be achieved for the risk involved.*

These are the principles underlying my comments to the subcommittee today. On the details of the President's proposal, Mr. Chairman, Merck has a number of very specific concerns. I will address these in a few minutes.

#### **INNOVATION REQUIRES SUSTAINED INVESTMENT**

In the pharmaceutical industry, the process of innovation can be likened to a pipeline which is open at both ends. At one end, the old products flow out; their patents expire and they enter the public domain *where they are copied and priced as commodities*. At the other end, the new products flow in. If the new products do not flow in, or if they do not measure up to the expectations of the health-care market, then the pipeline becomes empty and we as a business simply cannot survive.

For several reasons intrinsic to pharmaceutical research and development, maintaining the flow through the pipeline requires a sustained, long-term investment of resources to maximize the potential for innovation.

First, the odds against getting a compound to market are overwhelming. We design, selectively screen and manipulate thousands of substances and compounds. Very few will prove safe and

effective enough to be marketed for human use. It is painstaking research where failure occurs every day.

Second, is the time factor. A child entering first grade could graduate from high school in the average time--10 to 12 years--it takes to complete all the necessary, careful and costly research required to ensure that the product will benefit patients.

Third, market success is concentrated in a small number of prescription products. Duke University economists Grabowski and Vernon, looking at product introductions in the 1970s and early 1980s, found that 70 percent of marketed prescription medicines in this period did not recoup the average cost of R&D. Highly successful breakthrough products must earn a return that permits them to "carry more than their own weight:" they must recoup their own R&D costs; cover the costs of those that don't; and fill the financial hole left by all the R&D failures.

A case study in point on the inseparable link between sustained investment and innovation is the discovery and development of MEVACOR, Merck's breakthrough drug for patients with high cholesterol. An abbreviated chronology begins in the early 1950s, when Merck researchers undertook an investigation of the biosynthesis of cholesterol. Numerous targets were identified and numerous studies were done in an attempt to interfere with the body's production of cholesterol. In 1975, a key enzyme was identified that regulates the rate of formation of cholesterol by the body. However, it was not until 1979 that we isolated MEVACOR, and filed for a patent. Then began the long process of pre-clinical work and large scale clinical trials. Finally, on August 31, 1987, some 30 years after we began our effort, MEVACOR was given Food & Drug Administration (FDA) approval for patients with high cholesterol levels that could not be reduced by diet.



But the story of investment continues. Since the early 1980s, Merck researchers have worked to uncover possible benefits of MEVACOR for patients with atherosclerosis, which is a leading cause of heart attack and stroke deaths in this country. As a result of this research, Merck has received an FDA labeling change which states that lowering cholesterol with MEVACOR may actually cause *regression* of atherosclerotic plaque in some patients.

This is a major advance, because it is the first time that a single drug has been shown to reverse the clogging of arteries. Our research in this area, which involves over 6,000 patients, will continue through 1998 to determine if this regression can actually be linked to a reduction in deaths from heart attack and stroke. While this research is not related to producing a new product, it is precisely the type of further investment which can dramatically benefit patient health by discovering new uses for our products and reduce health care costs in the future.

In strict economic terms, lacking the investment incentives of a free market where we are able to fairly price our products, make them available to all who need them--and earn a profit--we might not have undertaken the research at all. If Merck had shut off permanently--or screwed too tightly, or too soon--the investment valves during this long, tortuous and risky process, the world still might be waiting for MEVACOR.

The same thing is true today for our AIDS research program. This program began in 1986 and is our largest ever. We have used the most modern disciplines of molecular virology and chemistry to design and test numerous drug candidates. During this period we have advanced five of these compounds to human trials, where four have failed. The fifth is currently in early clinical trials. To date, our investment in AIDS research is in excess of the \$359 million "average" cost cited to develop a new drug by the Office of Technology Assessment (OTA)--and is rising everyday. A breakthrough may be near but only time and additional investment will tell.

### A FREE MARKET FUELS INNOVATION

Research and development by American companies dominated at least eight critical therapeutic categories of major global drugs, including anti-infective, neurological, respiratory, cardiovascular and blood clotting. The General Accounting Office (GAO) studied 11 U.S. high-technology industries and in a report released last fall cited the pharmaceutical industry *as the only one in which U.S. firms maintained their international competitiveness in the 1980s*. The International Trade Commission attributed the U.S.'s strong position in the world market primarily to a "relatively unencumbered" economy "which has not to date implemented price controls on pharmaceuticals."

We also attribute our position in the world market to a climate that combines a sophisticated scientific infrastructure with a market offering the incentives and rewards necessary for *innovative* research and development. We have seen what a change in one of these two climate controls can mean for the pharmaceutical industry in Canada and Australia. Both countries have had the necessary technology and talent but R&D progressively has been switched off in both with the implementation of price controls. <sup>1</sup>The same is true with many countries in Europe. *We must not make the same mistakes in the United States.*

### A FREE MARKET ENGENDERS CHANGE

Mr. Chairman, it is the inherent responsiveness of a free market economy to public demands that has yielded radical reforms in the pharmaceutical industry. Market demands for high quality medicines, at competitive prices, have irreversibly changed the dynamics of the pharmaceutical industry in the 1990s.

Specifically, marketplace competition has driven down annual drug inflation in the years 1990 to 1993. The marketplace, coupled with current trends in voluntary price restraint, has brought

*pharmaceutical prices into line with the Consumer Price Index (CPI).* Merck is especially proud of the role we have been able to play in contributing to price moderation through our voluntary pledge, first made in 1990, to keep our overall price increases in line with the CPI.

Increased competition and consolidated purchasing power have a direct impact on marketplace dynamics. Just eight years ago, large customers, including HMOs and the government, accounted for about 30 percent of Merck's sales; today about half of our drugs go to that market. We expect this to grow to 60 percent by 1996. Large managed care customers have clearly demonstrated their ability to negotiate lower prices from manufacturers and generally manage drug benefits in ways that reduce overall costs while enhancing the quality of patient care.

Merck hopes to further cement this new merger of medical science and cost management through its acquisition of Medco Containment Services--the country's largest prescription drug benefits management company. Our vision is to create the world's first coordinated pharmaceutical care company that will optimize the discovery, development, selection, delivery, utilization, and value of prescription drugs. Our services will actively involve physicians, patients, pharmacists, payors and manufacturers in the drug benefit cycle with the ultimate objective of offering the best medicines, for the best patient health, at the best possible price.

Several other market trends are worth noting here as well. For the past two years, 87 percent of new drugs entered the market at prices lower than those for existing competitive products, including Merck's only entries, ZOCOR and PLENDIL. Since 1990, there has been a decrease in the annual growth of industry revenues, from 17.7 percent to 11.1 percent estimated for 1993--a decline of almost one-third. And during the current decade, patents will expire on over 200 drugs with combined 1991 sales of \$22 billion. As a result, the share of prescriptions claimed by low priced generics will increase to 50 percent, up from 30 percent today.

Unfortunately, these dramatic shifts in pricing and market behavior--and the hard management decisions they create--*too often are obscured by outdated rhetoric about obsolete patterns of operation.* Yet it is critical to recognize that change is happening and that the momentum for further change is embodied in free market reform initiatives, not top-down regulatory controls.

### CASH FLOW DRIVES R&D

In addition to market incentives needed to pursue innovative research and development, there must be the financial ability to do so. It is cash flow--the profits remaining after expenses, capital investment and taxes--that drives our ability to fund R&D. Whereas R&D *project decisions* are based on expectations--like the probability of a breakthrough drug--R&D *investment decisions* are based on cash flow.

Numerous academic studies have documented the responsiveness of R&D to changes in cash flow: for every \$100 drop in cash flow, R&D investment declines \$30 to \$40. This symmetric relationship of cash to commitments for research is particularly relevant today, Mr. Chairman, since dramatic market changes and federal legislation already have tightened the tourniquet on industry cash flow.

Revenue reductions already occurring in our industry will take their toll on R&D. That is inevitable. The pharmaceutical industry has been reducing expenses, shrinking employment and streamlining operations for several years now; we cannot continue to shield R&D while looking elsewhere for savings.

If cash flow is further constrained by regulatory pressures and price controls *as well as* by the changing marketplace, firms are likely to make far more significant cuts in their R&D budgets. As regulations roll out, Mr. Chairman, research dries up. I can assure you that the incentive to do pathbreaking research and development will be destroyed. Firms do not know at the outset



whether research will yield a major success or a dismal flop, so why would a firm tackle a new and risky disease if management could foresee artificially restricted returns?

In 1976 when I was head of Merck Research Laboratories, I made a decision to go forward with an expanded research program for enlargement of the prostate. Merck had been doing work in this area since the 1960s. However, a new development had just been reported concerning the clinical features of 5-alpha reductase deficiency--a key enzyme in the metabolism of testosterone. I had to decide whether to expand our program based on this information. Sixteen years later the result of that decision was the Merck drug PROSCAR, the first drug to reverse the overgrowth of the prostate in men.

But let me go back to 1976 when I made the decision to expand our research in this area. At the time, Merck had an exciting research program on potential new medicines. Just as important, we were operating in an environment that allowed the marketplace to value new pharmaceutical products. There was no National Advisory Council on breakthrough drugs; the Secretary of HHS did not have the authority to blacklist drugs; and 17 percent general rebates and additional rebates on new products for Medicare were not erasing one-quarter of my research budget. In addition, OBRA '93, Medicaid rebates, price discounts mandated in the Veterans Health Care Act of 1992 and prescription drug user fees implemented in 1992 did not exist. Neither did the expected \$14.5 billion in costs and lost revenues to our industry from these later items.

I knew that the decision to begin an expanded research program was a risky one. But I also had confidence that the cash flow from future sales of innovative medicines would provide the necessary dollars to fund this high risk research. Would I make this decision today in light of the events that have occurred since 1986 and what is envisioned in President Clinton's health care reform proposal? As a physician -- yes. But as a fiduciary of company assets for my shareholders -- probably not.

Today Merck and other American pharmaceutical companies have active, aggressive research projects underway in the areas of Alzheimer's, cancer, arthritis, AIDS, diabetes, osteoporosis and cardiovascular disease. The estimated annual cost of treating these diseases is \$380 billion, over one-third of total expenditures on health care in the U.S. in 1992. Pharmaceutical products to treat or prevent these diseases could result in significant reductions in health care costs and more importantly, save lives. At Merck alone thousands of scientists will work millions of hours, to design and test many substances and conduct increasingly numerous clinical trials to try to discover and develop the rare compound that eventually becomes a prescription drug. *But there must be economic incentives to do so.*

If industry steps back from the plate, who will step forward? Who will generate the scientific knowledge that emanates from the R&D process? And who, at the end of the process, will shoulder the responsibility and the expense for the massive clinical trials to demonstrate product value and generate further information about disease management?

Keep in mind that to reverse the process—to reactivate innovation—would take an estimated 10 years. That's the time required to rebuild our research organization. We cannot just flip on the lab lights and resume productive research if government decides to deregulate.

#### STRAW MEN AND PUBLIC POLICY

Merck believes that pharmaceuticals are a critical component of structural reform of our nation's health care system. Properly prescribed and administered, they are the most efficient health care intervention, one that produces real savings for the overall system. Already we see an increased concentration of buyers and an increased cash flow squeeze on providers as buyers wield their clout for more price concessions. Yet despite all the evidence that the market is working, there is intense political pressure to "do something" in particular to rein in pharmaceutical costs. *Through*

*a myopic focus on drug prices, Congress risks short-sighted policy development and could sacrifice the legitimate role of pharmaceuticals in reducing overall health care spending.*

Remember, Mr. Chairman, if you took away the industry's entire profits, Americans would save \$ .01 cent of the health care dollar--an impact on health care costs that would be lost in the rounding. But the impact it would have on the quality of life for people today and future generations would be felt forever.

Again, we need to focus reform on the part of our health care system that is broken. The true challenge lies in adequate insurance coverage. Such coverage is particularly needed for retirees living on fixed incomes, for Americans living at the poverty level, for individuals of ordinary means with extraordinary medical needs and others for whom purchasing prescription medicines can be a serious financial burden. Meeting their needs is a challenge to us all--the pharmaceutical industry and society in general, including government.

#### CONCERNS WITH THE CLINTON PLAN

The Health Security Act put forward by President Clinton proposes to respond to this challenge in several ways, including making prescription drug coverage part of the basic benefits package. We strongly support this provision. We also understand and applaud the Administration's intent in creating a Medicare outpatient drug benefit.

However, the Administration's Medicare outpatient prescription drug proposal embraces what we would regard as antiquated and counterproductive approaches to cost control, administered from Washington by the Secretary of Health and Human Services (HHS). Specifically, we are deeply concerned with provisions which:

- Require physicians to get permission from government bureaucrats in order to prescribe certain products;

- Establish an inflexible legislative formula for a minimum 17 percent rebate from manufacturers regardless of any other circumstances;
- Permit product blacklisting according to vague criteria.

Moreover, because the Administration plan would make *Medicaid* participation contingent on agreeing to these *Medicare* requirements, the Secretary of HHS would gain direct control over as much as 50 percent of the prescription drug market in the U.S. This degree of artificial market manipulation will have a chilling effect on research and development because the *incentive* to do pioneer work will have been reduced.

Mr. Chairman, we have developed an alternative proposal for a Medicare outpatient drug benefit patterned on the proven successes of benefit managers--including *pharmacy benefit* managers--to control costs while maintaining the quality of patient care. We believe our approach actually costs less than the program outlined in the Health Security Act. At the same time, it preserves the free market climate that promotes investment in pharmaceutical research and development. We will be happy to discuss our proposal with your staff.

The President's plan also calls for the creation of an Advisory Committee in HHS to review the prices of "breakthrough drugs." In all cases, the use of these breakthrough products has resulted in a net savings to the health-care system, by reducing the need for more costly alternative therapies such as surgery, hospitalization and additional doctor visits. It is equally important to note that "breakthrough drugs" rarely enjoy market exclusivity for very long. Most have follow-on competition within just three or four years, virtually all of which are priced lower. The impact of these follow-on products has been clearly demonstrated in a recent study by the Boston Consulting Group, which found that prices for new products approved and launched during 1991-92 were on the average 14 percent lower than the leading product in the same therapeutic category.



In other words, private sector competition already is providing the means to lower prices for "breakthrough drugs," so a board is not necessary. At best it will be superfluous and at worst it will actually dampen a manufacturer's willingness to invest in the high risk research and development of breakthrough drugs.

In addition, there is a provision in the bill which appears to be aimed at eliminating discounting-- by requiring that all parties which purchase the same volume of a prescription drug product be entitled to the same discount. This provision, which I will refer to as unitary pricing, is very problematic because it is essentially a form of price regulation. As I mentioned, it is clear that competitive forces in the marketplace are delivering cost savings to consumers. Price regulation, such as unitary pricing, is not justified and is fundamentally unfair.

Overall price regulation in the form of insurance premium caps is also very problematic. Such strict caps would force insurers and providers to reduce costs--and services or products--in a manner which may be inconsistent with good medical practice.

Finally, a word about "windfalls." Some proponents of the Administration's bill have argued that expanded coverage for pharmaceuticals will significantly boost industry sales, thus offsetting any losses due to rebates and other controls. This simply is not the case. Two recent studies, one by Lewin-VHI and a second by former CBO analyst Don Muse of the Policy Research Group, estimate revenue losses of between 5.9 percent and 11.2 percent for brand name companies under the President's plan.

**CONCLUSION**

Mr. Chairman, I want to reemphasize Merck's strong support for constructive health care reform. As we attempt to sort out what is right and what is wrong with our health care system, it is vitally important that we recognize that innovation is part of what is right. Innovation has made America a world leader in medical technology and has yielded an abundance of new products that save lives, reduce human suffering and improve the quality of our daily living.

Mr. Chairman, the same free market system that has made the U.S. a global leader in pharmaceutical innovation is likewise providing society with the tools it needs to control health-care spending--including spending for prescription drugs. As we move forward on health care reform, we should endeavor to capitalize and build upon these important private sector initiatives, not stifle them with a highly regulated government-run system.

I thank you for the opportunity to testify today and look forward to any questions.

Mr. WAXMAN. Mr. Raab.

### STATEMENT OF KIRK RAAB

Mr. RAAB. Thank you, Mr. Chairman. I'm Kirk Raab and I'm President and Chief Executive Officer of Genentech. I'm Chairman of the Biotechnology Industry Association, representing over 500 companies, and I'm Chairman of the California Health Care Institute.

I would like to make three major points.

We believe that health care reform is imperative and we think that a drug benefit should be a part of it.

Second, we believe that real or disguised price controls on the products that bring the most innovation will bring unnecessary risk to patients.

Third, we think the goals of improved health care quality and cost containment can be achieved with adoption of alternatives to the administration's proposals.

There has been often too much, I believe, in discussion of health care reform referred to from polis and from mythology. I would like to address four facts.

The first fact is clearly we do not have enough treatments and cures for cancer, for AIDS, for arthritis, for Alzheimer's, and diseases of women, and we can't do anything that will slack off the energies to find these solutions.

The second fact. We all welcome, as Dr. Vagelos says, the funding and activities of the National Institutes of Health. But cures and vaccines are produced in bottles, little bottles of stuff, and it's the private sector who produce these bottles to provide the prevention and cures.

Third, the biotechnology industry has been hurt. Our capitalization, our value is down 30 percent. IPO's are down in numbers and the quantity of money raised. And most importantly, new clinical trials begun in 1993 were down 10 percent, the first decline in 5 years.

The fourth fact. The marketplace is working. Price restraints are happening and companies are studying the real value of their products to patients and to systems. Our new drug for cystic fibrosis, Pulmozyme, has been mentioned a number of times today. This is the first product specifically for cystic fibrosis introduced in 30 years. We did in our phase III clinical trials outcomes research that showed this product saves money on antibiotic usage and on hospitalization days. We have also committed to pricing it equally throughout the world and to limiting our price increases to the CPI.

Biotechnology industry supports comprehensive bipartisan health care reform, but we think it must be designed in a form that will stimulate the creation of products that are the best hope of the patients of America.

I have two objections to the administration's proposals. I don't think either one will be a surprise to you.

The first is the Breakthrough Drug Committee. In my opinion, it will discourage risk taking; it will discriminate against innovation; it will cost lives and dollars; and it will slow down investment in research and development.

Second, I think the coerced pricing decisions enabling the Secretary to set prices through various mechanisms related to rebates will do nothing but harm this industry. Our industry can deal with scientific risk; we can deal with regulatory and market risk; but we can't deal with a risk of financial controls by the government.

Let me conclude by saying that when you mark up this bill, I ask the committee to determine that this or that provision will increase or decrease the likelihood of cures for patients who have these terrible diseases. I think you will find when you apply that standard and look at the administration's proposals that you will reject the Breakthrough Drug Committee, that you will find more funding for outcomes research, as Congressman Wyden has addressed, is very important, that you will motivate the private sector to deliver drug benefits, as it can do most efficiently and most effectively, and finally, the price controls in their veiled form in this legislation will do terrible harm to our industry.

I look forward to working with the committee and responding to your questions afterwards.

Mr. WAXMAN. Thank you very much, Mr. Raab.

[The prepared statement of Mr. Raab follows:]



STATEMENT  
OF  
KIRK RAAB  
PRESIDENT AND C.E.O OF GENENTECH  
ON BEHALF OF THE  
BIOTECHNOLOGY INDUSTRY ORGANIZATION  
  
BEFORE THE HEALTH AND ENVIRONMENT SUBCOMMITTEE  
OF THE  
ENERGY AND COMMERCE COMMITTEE  
FEBRUARY 8, 1994

Good morning, Mr. Chairman and members of the subcommittee. I am Kirk Raab, President and CEO of Genentech, Inc. and Chairman of the Board of the Biotechnology Industry Organization, a group that represents more than 525 companies and service organizations in 47 states. I want to thank the Subcommittee for the opportunity to testify at this hearing. I would like to talk to you today about my industry and health care reform.

THE BIOTECHNOLOGY INDUSTRY

We are a relatively young industry which began only 20 years ago in the United States when American scientists discovered that they could recreate human proteins to diagnose, treat or cure diseases. In the past 15 years scientists working at the frontiers of human knowledge have created new products to treat diabetes, cancer, heart attacks, human growth deficiencies, renal insufficiency and many other afflictions. So far, 27 biotechnology therapeutics have been brought to market with total sales of \$1.9 billion in 1992. Almost all of them are medical breakthroughs that treat serious medical needs which had not been met. Because of our biotech medicines, children lead normal lives, cancer patients survive and heart attack victims live.

There are 1,300 biotechnology firms in the United States today employing approximately 97,000 people at salaries that average approximately \$30,000 a year. These are precisely the kind of high-paying, high-tech jobs that the President and so many others advocate for our country's future. In some parts of the United States, most notably your state of California, Mr. Chairman, biotechnology companies have accounted for significant percentage of new jobs. According to the California Health Care Institute, more people in your state are employed now by the biomedical industry than the computer industry. Small companies, those with fewer than 50 employees, have created 10 percent of the new jobs in California in the past four years.

### **RESEARCH AND FINANCE**

American biotechnology firms have an extraordinary commitment to research and development. Our firms spend more on research and development as a percentage of sales and per employee than any other industry. R & D spending represents 81 percent of sales and \$59,000 per employee. To date the biotechnology industry has spent some \$10 billion seeking to understand the basic mechanisms that underlie diseases and on designing specific therapies to combat them.

To survive and continue their research on some of the most serious diseases, biotechnology companies must have access to the equity capital markets. Unfortunately, despite our industry's great success in saving lives and improving the quality of life, most

biotechnology companies are struggling to survive financially. In fact, less than 1 percent of biotechnology companies in the United States earn any profits at all. A report by Ernst & Young found that the industry has lost nearly \$10 billion since its beginning.

So, it is these financial markets, not profits from the sale of drugs, that support the biotechnology industry. The investors are mostly middle income people who participate invest in the industry through mutual funds and pensions funds. In 1993 the biotechnology industry spent \$5.7 billion on research and development; 90 percent of that spending was paid for by these investors.

In 1994 the biotechnology industry should be looking toward a promising future. We should be anticipating new breakthrough drugs that will revolutionize the treatment of AIDS, cystic fibrosis and cancer, to name just a few diseases. We should be envisioning tantalizing new cures, perhaps even the prevention, of intractable illnesses through the human genome project, now proceeding ahead of schedule.

I say "should," Mr. Chairman and Subcommittee members, because, instead of eagerly working toward that future, our industry is being jeopardized by a crisis that has been precipitated largely by the government and the health care reform proposals that are now pending before your Subcommittee. Investors have been scared by the prospect of government price controls that target breakthrough drugs. Investors are worried that they will be denied a fair return on their investments and may even lose their capital. This fear

has had a direct, negative impact on our industry.

Biotechnology companies were able to raise a total of \$2.8 billion in the capital markets in 1993, compared with \$2.5 billion in 1992. However, if you look closer at these aggregate totals, you will understand why only segments of the capital market were open and that the cost of capital increased. A significant portion of the money that was raised last year was in the form of private placements. Taken together, venture capital firms, institutions and even individuals came up with a full 40 percent of all monies flowing to biotech in 1993. Venture capital and private placements are usually seed money that allow companies to begin their research. When a venture capitalist invests in a company, he/she is investing in the science of biotechnology. As a company gets close to commercialization of a product, it usually must go public to raise funds from shares traded on the NASDAQ, NYSE or AMEX stock exchanges. The public stock market is the only place that they can go to raise the enormous amounts of money that are needed to commercialize a product. This type of capital, sometimes labeled "mezzanine" financing, is invested by people who are backing a potential biotechnology product.

Public financing was especially difficult for biotechnology companies in 1993. The American Stock Exchange Biotechnology Index lost 32.6 percent last year. These difficulties are further displayed by figures comparing this year to last year in terms of total public offerings and initial public stock offerings (IPOs). The average deal size of public offerings in 1993 was down to \$23 million, from \$28.2 million in 1992. IPOs were down to \$22



million in 1993, compared with \$26 million in 1992. Several public biotech companies were forced to do Private Investment in Public Equity (PIPE) financings, deals where public companies sell stock to private investors at a discount to their current stock price. Many mezzanine investors were scared by the de facto price controls in the Administration's healthcare plan because they perceived it to mean that they would not recoup their investment in a company that was close to bringing a product to market.

There is a human cost to all of this. Important research has been delayed or abandoned because companies can not raise the funds to undertake it. Companies are imposing hiring freezes and laying off scientists. Millions of lives that might have been saved or immeasurably enriched by research in the next five or ten years will not be. In San Diego, California, Viagene was pursuing promising research on a drug that enhances a patient's ability to fight viral infections, including the virus that causes AIDS. Now Viagene has cut back on its clinical trials. In Portland, Maine, ImmuCell is delaying research on a medicine for infants who suffer from life-threatening dehydration. In Princeton, New Jersey, Cytogen Corp. has postponed human testing of its diagnostic products for breast and lung cancer. Cytogen President Thomas J. McKearn told a reporter that "approximately all" of those decisions were a direct result of the Clinton plan.

There is a risk in investing in our industry. Nine out of ten research projects never produce a drug that can be marketed. To compensate for that risk, investors must see that it is possible for them to receive fair return or they will go elsewhere. As a result the industry

may be unable to produce the next drug. This is not just the opinion of our industry. Last fall the Cystic Fibrosis Foundation and the Alliance for Aging Research, both independent not-for-profit organizations, wrote the President warning that the proposed pricing mechanisms would threaten the lives of two of our most vulnerable population groups, children and the elderly.

### **DRUG PRICING**

We are concerned that our industry has been singled out for the pricing mechanisms while managed care and global budgets are deemed sufficient for all other segments of the health care industry. Existing drugs are not included in this proposed review. It is only innovative drugs that are penalized.

Drug prices get a lot of attention because, unlike doctor and hospital bills, most Americans pay for their prescription out of their own pocket. This is understandable but unwarranted. Only 7% of the cost of health care in America comes from the cost of drugs, \$56.1 billion out of \$823 billion. Only 3.4% of this 7% comes from the breakthrough biotech drugs, \$1.9 billion out of \$56.1 billion. We could completely eliminate the cost of every one of these drugs -- not just the profit, but the total cost -- and it would have a trivial and imperceptible impact on total health care costs.

### **HEALTH CARE REFORM**

The drafters of the health care reform proposal fail to understand the nature of our

industry, particularly the expense of researching and bringing a new drug to market. It takes on average 10 to 12 years to develop a new product. The average cost of development is \$350 million, according to the Office of Technology Assessment. And that \$350 million must be expended before a single product reaches the neighborhood pharmacy. Yet, research costs are last on the list of things that the proposed Council and HHS Secretary are to consider in determining the reasonableness of a breakthrough drug's price. They are not mentioned at all in relation to rebates on Medicare drugs.

Let me hasten to add here that the biotechnology industry is concerned about prices and has worked since its inception to ensure that patients have access at a reasonable cost to its products. Virtually no biopharmaceutical drug has increased its price beyond the rate of inflation. Our medicines tend to be priced two to three times higher abroad than here in the United States. Most have NEVER had any price increases at all and some have actually declined in price. Moreover, the manufacturer of every biopharmaceutical has instituted a "free goods" program to ensure that no American is denied treatment because of inability to pay.

Although biotechnology drugs may be expensive, precisely because they are breakthroughs resulting from the investment of millions of dollars, they can be cost-effective. For example, the drug Betaseron is expected to dramatically reduce the number of times that patients with multiple sclerosis must be hospitalized, more than compensating for the annual cost of the drug. Instead of driving up health care spending, the biotechnology industry

offers the best hope of containing future costs.

We are alarmed by three proposals in the Administration plan that may not be direct price controls but, taken together, are tantamount to them. The Advisory Council on Breakthrough Drugs would examine the launch price of new drugs--and only new, breakthrough drugs--to determine their reasonableness. The Secretary of Health and Human Services would have the authority to negotiate "special rebates" on these drugs and to deny reimbursement for those drugs if the price is not "reasonable," in effect, to blacklist them. In addition to these provisions, specifically targeting the biotechnology industry, the proposals require that drug manufacturers give the government a special discount of at least 17 percent on the price of all drugs sold to Medicare patients or risk being blacklisted. It is these proposals that have driven away investors and placed the biotechnology industry in peril.

Because of our confidence in the value of our drugs and our concern about health care costs, we support efforts to evaluate the usefulness of technology as long as it includes ALL modes of treatments--procedures, devices, drugs, biologicals and diagnostics--and doesn't discriminate against new technology such as biopharmaceutical drugs and in the process stifle innovation. Instead of creating a new bureaucratic entity to oversee one small segment of the health care industry, Congress might assign this responsibility to an already existing government body, the Agency for Health Care Policy and Research (AHCPR) that was created in 1989. AHCPR is authorized to study the safety, efficacy and cost-effectiveness of



all medical treatments and technologies. This approach would ensure that several important principles would be used: (1) all technologies and procedures, both old and new, would be evaluated; (2) technology assessment would not be the responsibility of an agency that is also charged with cost containment; and (3) decisions would be based solely on the evidence that a specific therapy does or does not present a meaningful clinical advantage.

### CONCLUSION

The biotechnology industry can and does support many of the Administration's health care proposals. Important changes are needed in our health care system so people who are ill have full and fair access to treatment. In particular, we commend the proposals for providing a drug benefit for all Americans, the portability of health insurance and the elimination of preexisting condition clauses in insurance policies.

In conclusion I want to appeal to you to recognize the unique nature of our industry and the benefits it can deliver as long as it has access to the financial markets to fund research. I thank you for the opportunity to appear before your committee. I'll be happy to answer any questions.

Mr. WAXMAN. Dr. Sanders.

### STATEMENT OF CHARLES A. SANDERS

Mr. SANDERS. Thank you very much, Mr. Chairman and members of the subcommittee. I'm Charles A. Sanders, Chairman and CEO of Glaxo Inc., which is, after Merck, the second largest research-based pharmaceutical company here in the United States.

I've been a participant in and observer of the American health care system for over 35 years as a cardiologist and clinical researcher, as a professor of medicine at Harvard Medical School, as general director of the Massachusetts General Hospital, and more recently as a pharmaceutical company chairman.

I am convinced that the health care that we have in this country is second to none, but I am also equally convinced that we need to add some reforms to the system. It's clear that we have to contain costs, we have to expand access, and we have to preserve and improve the quality of the care that we provide to our citizens.

My message to you today is really pretty straightforward. The best way to arrive at the health care reforms that we all want is to promote the sort of innovation that has made this country the biomedical research laboratory of the world, because with innovation you achieve both enhanced quality and cost savings. Innovation is the life blood of my industry. It's what we do. Whatever we find is what we are.

At Glaxo in particular we have invested \$1.2 billion in research and development worldwide in 1993, which incidentally is \$375 million more than our total revenues in the United Kingdom for the comparable period. And it is a level, by the way, which represents a 2,800 percent increase in R&D expenditures since we entered the United States market in 1979.

As a result of such investments like we have made, our industry can point to a number of extraordinary successes, some of which have already been alluded to by Dr. Vagelos and Mr. Raab. I have outlined some examples in my own written statement.

Mr. Chairman, as we embark upon the health care reform, we should build upon what is good in this present system. This is a particularly appealing reform strategy because it uses the market forces that work today and forces that already are reforming health care without waiting for specific legislation. These forces have already led to the lowest prescription drug prices in 20 years and to lower introductory prices of new drugs as well, albeit at the cost of restructuring in this industry, including 30,000 job losses and the lowest growth rate in R&D investment in 16 years. And these are structural changes. Such changes did not accompany the cost controls that I experienced as a hospital director in the 1970's.

We recognize that these changes are the inevitable consequences of a competitive system. Of concern, however, are the more profound and damaging effects that would result from the administration's version of managed competition, including an erosion of our ability to realize the promise of innovation.

A specific concern, as you already know, is the Advisory Committee on Breakthrough Drugs. I might point out that breakthrough drugs account for approximately 1/500 of the total health care expenditure in the United States today. Yet we are imposing the po-

tential, in the form of an Advisory Committee on Breakthrough Drugs, of creating unintended affects down the road.

We are also concerned about the HHS Secretary's power to blacklist medicines designed for the Medicare population.

Each provision, in effect, puts a government imprimatur on a specific pricing level.

Let me point out to you in follow-up to Dr. Vagelos' statement that this can very significantly alter our research strategy, because if we know going into an R&D project that our returns at best will be limited or that the hope for a compound at the end of the road might be denied to the very patient group it is designed to help, the elderly, for example, we would have to think very carefully about entering that project to begin with. The ultimate effect may be a bias away from long-term, high risk breakthrough projects to shorter term incremental low risk projects.

My company may provide a glimpse of how these forces would come together. Glaxo discovered and markets a medicine called Zofran, which controls the nausea and vomiting associated with cancer chemotherapy, and it has become the standard therapy to treat chemotherapy induced emesis in cancer patients across the country over the past 3 years.

Zofran is a result of basic research that began in 1972, basic research that had no guarantee of success. It was not until 1990 when Zofran was introduced in the market that we were able to realize a return on the 20-year investment in R&D.

Today it seems almost unimaginable that anything could have sidetracked that. Yet we have to ask ourselves if the project were beginning in an environment dominated by government regulation, would we pursue it?

Fortunately, I don't have to answer that question. Yet the fact remains many similar questions are around the corner, and if the answer to those questions is too often no, what kind of knowledge of breakthrough will be lost?

If the exigencies of a regulated marketplace and the realities of business cause investments in innovation to slow or shrink, which future project will get the funding? Will it be the one holding the potential to wipe out tuberculosis worldwide? Or will it be one that might save thousands of lives otherwise lost to AIDS? Or will it be the one that will prevent the tragedy of Alzheimer's? There is no simple answer.

I urge all of us as we go forward to enact reforms that keep the promise of biomedical innovation alive so that we may avoid ever having to ask these kinds of questions.

Thank you very much.

Mr. WAXMAN. Thank you, Dr. Sanders. I appreciate your testimony.

[The prepared statement of Mr. Sanders follows:]

## STATEMENT OF CHARLES A. SANDERS

**We exist to discover  
and develop innovative  
medicines to treat  
unmet medical needs,  
an effort to which Glaxo  
will devote \$1.4 billion  
worldwide this fiscal  
year.**

Mr. Chairman, I am Charles A. Sanders, M.D., chairman and chief executive officer of Glaxo Inc., the second largest research-based pharmaceutical company in the United States. Glaxo Inc. is a subsidiary of British-based Glaxo Holdings p.l.c., with U.S. headquarters, including a 1.5-million-square-foot research and development center, in Research Triangle Park, N.C. Glaxo employs more than 6,400 people in the U.S.

Like all health care companies, Glaxo has a keen interest in the ultimate shape of health care reform. We are interested because it obviously will affect our business, but more importantly, we are interested because it will affect our mission. We exist to discover and develop innovative medicines to treat unmet medical needs, an effort to which Glaxo will devote \$1.4 billion worldwide this fiscal year.

Because we are convinced that the products resulting from such research efforts will play an even more important role in high-quality, cost-effective health care in the future, we firmly support the inclusion of prescription drug coverage in the standard benefits package that likely will emerge from current reform discussions. It's especially important that this coverage be extended to those covered by Medicare, who consume a disproportionate share of all medical services, including pharmaceuticals.

Today I will explain how our mission to discover new medicines is consistent with the health care needs of this country, and in fact serves as the foundation for solutions to many of the problems that continue to vex our current health care system. I also will discuss how we might achieve the goals of health care reform in a manner that preserves the vital role of biomedical innovation. Finally, I will point out some concerns with aspects of the Administration's reform plan that might diminish innovation in the medical sciences and, along with it, the hopes of thousands of people suffering from diseases, like Alzheimer's, osteoporosis and cancer, that are inadequately treated now.

As a participant in and observer of the health care system for 35 years, I have gained a broad-based perspective on both the problems facing our health care system and on some of the potential pitfalls we may encounter as we seek to reform it. As a practicing cardiologist, and later as a professor of medicine at Harvard University, general director of Massachusetts General Hospital and now CEO of a major pharmaceutical company, I am convinced that health care in this country is second to none. However, I am also convinced that reforms are needed.

It is plainly not acceptable to allow 35 to 40 million uninsured Americans to live an ambulance ride away from financial ruin. It is plainly not acceptable to ration health care based on an individual's ability to pay. But it is also not acceptable to compromise the quality of the health care services we have come to depend on and can look forward to in the future.

It is clear that we must contain costs, expand access and preserve and improve quality, and I commend the efforts of President Clinton and Members of Congress who have offered various proposals to address these important issues.



According to Dr. John Fangman, head of the neonatology unit, use of the new lung surfactant drugs allowed them not only to scrap their plans for the new unit, but also to close their existing unit because the population of babies needing chronic care decreased so dramatically.

As we grapple with them, however, it is also not acceptable to overlook the vital role of biomedical innovation in providing solutions.

Whatever direction we take, we must recognize and encourage innovation, because innovation impacts every point of the cost-access-quality triangle.

As pharmaceutical companies make strides in unlocking the secrets of disease and in designing more effective medicines, innovation will enhance quality. As these new medicines keep more people out of the doctor's office, out of surgery and out of the hospital, innovation will help contain costs. As technological advances improve efficiencies in health care delivery, innovation will help expand access.

Recent history provides us with abundant examples, but I would like to focus on three, including two that originate close to home in North Carolina. The first involves a new medicine that is renewing hope for premature infants and their families. The second involves work at Duke University Medical Center in Durham. The third involves an innovative medicine produced by Glaxo.

Premature infants sometimes suffer from breathing difficulties that have come to be called respiratory distress syndrome (RDS). A new class of lung surfactant drugs developed by the pharmaceutical industry has helped thousands of babies overcome RDS and grow strong enough to leave the hospital and begin their young lives amid the security of home and family.

Not only is this new therapy saving lives, but it also is saving money by reducing hospitalization and the use of other resources formerly devoted to treating these children. For example, Minneapolis Children's Medical Center in Minnesota was planning to build a new unit for care of children born with chronic lung disease. According to Dr. John Fangman, head of the neonatology unit, use of the new lung surfactant drugs allowed them not only to scrap their plans for the new unit, but also to close their existing unit because the population of babies needing chronic care decreased so dramatically. By canceling the building project, the hospital saved at least \$4 million and was able to use their existing unit for other patient services.

Similar efficiencies are being achieved at Duke University in a bone marrow transplantation program where the use of a new therapy has had a dramatic impact on the lives of many cancer sufferers. Use of this new therapy has also turned what was a high-mortality, inpatient procedure into a highly successful procedure performed largely on an outpatient basis.

The Duke program has performed autologous bone marrow transplants on more than 850 patients. Under the earlier approach to bone marrow transplant, patients were required to spend weeks in isolation units while their bone marrow engrafted and began producing new blood cells. The cost per patient was about \$140,000 in 1990 and rising.

**Today, largely because of a product of biotechnology that stimulates the growth of bone marrow — a compound called granulocyte colony stimulating factor, or GCSF — most patients are able to be hospitalized for only 4-5 days, and the per-patient cost has dropped by \$75,000.**

Today, largely because of a product of biotechnology that stimulates the growth of bone marrow — a compound called granulocyte colony stimulating factor, or GCSF — most patients are able to be hospitalized for only 4-5 days, and the per-patient cost has dropped by \$75,000. Even more important, improved drug therapies are contributing to decreasing mortality rates, which in the program's first decade ranged from 21 to 25% in the first 100 days of treatment, compared to about 2 to 3% now. The value of biomedical innovation in this area was summarized by no less an authority than Dr. William P. Peters, director of the Duke Bone Marrow Transplant Program, who has cited his experience as "an example of where a new technology not only improved outcomes but decreased costs."

Improved outcomes and decreased costs are also being realized by hospitals using one of Glaxo's newer drugs, Zofran® (ondansetron hydrochloride), an innovative medicine that prevents the severe nausea and vomiting caused by cancer chemotherapy. While oncologists and cancer patients quickly realized its benefit, hospital officials concerned with cost containment are appreciating it for another reason spelled out in a Wall Street Journal article on November 3.

The article reported on efforts by a Michigan hospital to develop a treatment plan for cancer patients that would reduce costs without compromising the quality of care. The difficulty lay with patients taking a particular anti-cancer drug that, because of the violent retching associated with high doses, often left patients severely dehydrated and their kidneys subject to damage. A three- to four-day hospital stay was typically required to ensure the patient was sufficiently hydrated before his or her release.

By re-examining its treatment protocol, however, the hospital was able to reduce hospital stays to one night for 80% of their patients receiving the high-dose chemotherapy. Central to the success of the shorter stay, the article said, was Zofran®. The drug proved so much more effective than other therapies, "it's not even ethical to withhold it," said the physician in charge of the hematology/oncology unit. The article also noted that, at a hospital cost of about \$130 a dose, the drug "is much cheaper than a day in the hospital."

Each of these cases stands as a dramatic example of the payoff of biomedical innovation. But none is unusual. Each joins a host of other achievements demonstrating the same effect: cardiovascular drugs that allow patients to avoid \$40,000 coronary bypass surgery; psychotropic drugs that reduce schizophrenia patients' need for institutionalization and other treatment, saving costs of \$25,000 per patient per year; ulcer drugs that have made expensive and uncomfortable gastric surgery largely a thing of the past.

My purpose here is not simply to provide a laundry list of solutions to health care problems made possible by pharmaceutical industry innovation, although the effects of the innovations are clear. Rather it is to point out that these innovations were not coincidence. They were the direct result of significant investments undertaken with innovation as the goal, with the clear expectation of reward should innovations result.

Since entering the U.S. market, however, Glaxo's investments worldwide have increased more than 2800%, supporting the research and development of innovative products like Zofran.

In addition, our R&D investments have allowed Glaxo to build and equip a 1.5 million-square-foot research center in North Carolina, part of a capital investment over the last 10 years of more than \$1 billion in the U.S. alone.

It is not coincidental that of the 97 new drugs marketed worldwide in the 15 years ending in 1989, 47 originated in the U.S. It is not coincidental that a 1992 General Accounting Office report examining global competitiveness of 11 major U.S. industries cited the pharmaceutical industry as the only one that had maintained its leadership position throughout the 1980s. It is not coincidental that industry analyst Heinz Redwood concluded that "the American pharmaceutical industry has a clear and outstanding lead in developing major, medically innovative, globally competitive and therapeutically accepted new drugs" and that there exists "an indisputable link between pricing freedom and successful innovative research and development in the pharmaceutical industry."

While the U.S. has earned a leadership role in pharmaceutical innovation, it is clear that productive research also occurs in companies based in countries with some sort of government mandated price restraint. It is also clear, however, that to sustain the increasingly expensive investments necessary for continued discoveries, the major players in the international pharmaceutical industry must have vigorous U.S. operations. My own company is an example.

Glaxo's worldwide headquarters is in the U.K., which controls profits based on capital investments in that country. This system rewards companies with a significant capital investment in the U.K., a situation that certainly applies to Glaxo. Therefore Glaxo was able to maintain needed investments in innovation even before its first product became available in the United States in 1979.

Since entering the U.S. market, however, Glaxo's investments worldwide have increased more than 2800%, supporting the research and development of innovative products like Zofran. Indeed, in fiscal 1993, our R&D expenditures exceeded the total revenues realized in the U.K. by more than \$375 million.

In addition, our R&D investments have allowed Glaxo to build and equip a 1.5 million-square-foot research center in North Carolina, part of a capital investment over the last 10 years of more than \$1 billion in the U.S. alone. Our number of employees in the U.S. has grown to more than 6,400, as I mentioned before. And we are one of the largest taxpayers in North Carolina.

Such investments make prescription pharmaceuticals part of the solution to the health care issues we face today in this country. They have achieved that status because we operate in a free market that rewards the high-risk enterprise of pharmaceutical discovery and development. So if we accept, first, that this country's competitive market has allowed the U.S. industry to become the world's leader in the discovery of innovative medicines, and, second, that we must achieve the cost-containment, access and quality goals of health care reform, the question becomes how to reconcile these sometimes competing agendas.

Mr. Chairman, we have a model for comprehensive reform that will allow us to reach all of our shared goals. It is the concept of market-based managed competition originally advocated by the Jackson Hole Group, in which I have been an active participant. That concept has been embodied in legislation sponsored by Congressmen Cooper, Grandy, McMillan, and others. The strength of this

In a health care system in which a pharmaceutical company's ability to realize returns is less certain, the industry simply will not be able to continue its current approach to investments in innovation.

approach is that it relies on the marketplace and builds on many of the changes that are already occurring to widen access and further contain costs. Importantly, because market forces would not be substantially impeded, it also would preserve the incentives for innovation that will be the key to overall cost savings in the future.

These market forces have led to the lowest prescription drug price increases in twenty years. In addition, many new products in established therapeutic categories are being introduced at prices well below the category's market leader. Unfortunately, these forces have also led to over 30,000 job losses in the U.S. industry, representing a work force reduction of more than 10%. In addition, they have slowed the rate of growth in private R&D investments, with the 1993 increase in R&D budgets the smallest in 16 years.

Enactment of health care reform legislation based on the principles of market-based managed competition may lead to further significant adjustments in the way the pharmaceutical industry approaches its discovery, development and business practices. We recognize, however, that under meaningful reform all players in the health care industry must accommodate change. So while the changes would be challenging, they are reasonable if we are to reach our health care reform goals.

Indeed, the changes already taking place in the U.S. health care industries are evidence that the marketplace is far ahead of the rest of us in this area. They are proof that health care reform is already taking place, especially in the pharmaceutical industry. It is now the challenge of society in general and Congress in particular to arrive at a plan that will build on these incremental changes in a positive way to further the cost-access-quality goals of reform.

If we are successful in that effort, we will maintain the incentives for innovation that are so essential for continued biomedical advances. The pharmaceutical industry's ability to deliver those advances is far less certain, however, under some of the provisions of the Administration's version of managed competition. While the proposal's incorporation of the terminology and some of the structures of managed competition is encouraging, its reliance on regulation is concerning. Especially concerning are the price controls, both implicit and explicit, that would fundamentally change the economic equation in health care delivery. They also would change fundamentally the nature of the industry's decisions about what sort of research and development to pursue.

It is a sad fact that many of industry's research projects never make it out of the lab, yet consume enormous resources before enough is known to decide whether to proceed or abort. With such failures an unfortunate part of life in biomedical research, the ability to realize fair returns on successes is crucial. In a health care system in which a pharmaceutical company's ability to realize returns is less certain, the industry simply will not be able to continue its current approach to investments in innovation. One telling indication of this is the slowdown in the rate of growth of the industry's R&D budgets, which I mentioned earlier.



Unfortunately it is extremely difficult, perhaps impossible, to know what the 'right' price for a breakthrough drug is," Ms. Wagner said. "Every criterion for evaluating the entry price of a new drug is problematic. For example, even at high prices, some breakthrough drugs may save overall health care costs by reducing the need for other expensive care."

Contributing to the uncertainties are the enormous powers given to various offices and entities in government. Among the most concerning is the authority given to the National Health Board to establish and enforce global budgets through control of premium rates.

Such budget caps would inevitably lead to a cost-focused line-item approach to medical decision-making, forcing trade-offs of costs vs. quality.

An example of the effect is the 30-year-old patient with high cholesterol, but who is vigorous and otherwise healthy. A formulary committee operating under a global budget may argue that it can't justify coverage of lipid-lowering medications. Such coverage would only add to this year's expenditures, with no discernible improvement at year's end in the patient's health. The patient still suffers from high cholesterol; he still must take the medication. Unexamined are the questions of how the lack of coverage today will affect this patient in 10 years. Will coronary bypass surgery be required? How much greater will his health care costs be over his lifetime?

As a developer of innovative drugs, we recognize that formularies will remain part of the health care landscape for some time to come. However, the interests of patients, physicians, budget directors and pharmaceutical companies all would be served by formularies that consider not just acquisition costs, but also overall economic and quality-of-life outcomes. Artificial budget caps force a distortion in health care decisions that may well lead to higher costs over time.

Similar concerns are presented by the proposed Advisory Committee on Breakthrough Drugs. This is a panel that would be empowered to examine the launch prices of new drugs that represent significant advances over existing therapies. It would determine the "reasonableness" of the price by studying, among other things, projected prescription volume, manufacturing costs and research expenditures.

There are tremendous difficulties with this approach, a fact recognized by Judith Wagner, senior associate in the health program of the Office of Technology Assessment, in her comments last November to the Senate Special Committee on Aging. "Unfortunately it is extremely difficult, perhaps impossible, to know what the 'right' price for a breakthrough drug is," Ms. Wagner said. "Every criterion for evaluating the entry price of a new drug is problematic. For example, even at high prices, some breakthrough drugs may save overall health care costs by reducing the need for other expensive care." At the same time, she recognized that "many breakthrough drugs will offer major improvements in mortality or morbidity but at a net increase in health care costs even when the price is at the minimal level required to assure its availability on the market."

Putting aside these difficulties, putting aside the terrible precedent of a committee of this sort rummaging through a company's books, the power exercised by this so-called advisory committee would be extraordinary. While it would not have direct price-setting powers, it would be putting a government imprimatur on a specific pricing level. By emphasizing costs exclusively, it would discourage the health plans and individual physicians from considering the benefits of a

if, however, a drug company knows that after its huge investments of time and resources, the resulting compound may not be available to the very people for whom it was designed, it would have to consider carefully whether it wants to invest the time and money to begin with.

new medicine objectively and arriving at their own independent opinions of its value.

Perceptions of value are at the heart of another troubling aspect of the Administration's proposal, the provision that gives the Health and Human Services (HHS) Secretary power to blacklist a drug for the Medicare population. If the Secretary deems a new drug "inappropriately priced," he or she may exclude it from Medicare coverage, or negotiate an extra discount in addition to the one that would be mandated for all pharmaceuticals.

While Glaxo recognizes the importance of providing prescription drug coverage for the elderly, this provision conceivably could discourage research into pharmaceutical treatments for diseases affecting that portion of the population. These diseases — Alzheimer's, for example — are among the most puzzling to understand, and therefore are among the most costly to explore in terms of drug discovery and development. They also are among the most expensive in terms of costs to society. If, however, a drug company knows that after its huge investments of time and resources, the resulting compound may not be available to the very people for whom it was designed, it would have to consider carefully whether it wants to invest the time and money to begin with. Indeed, it may be the case that the entire market for some compounds lies within the Medicare population, making the negotiation with HHS not a true negotiation at all because of the unilateral leverage the Secretary would bring to the table.

The same considerations apply to the proposed Medicare rebate scheme, which adds an element to the R&D decision-making process that may tilt the balance further toward conservatism. The rebate seems to be predicated on the idea that companies will see a windfall of revenue from the increased use of pharmaceuticals in the Medicare population. Based on Glaxo's analysis, however, the induced demand will be far lower than that estimated by the Administration, largely because Medicare recipients as a group are already using pharmaceuticals. The Administration proposal would simply change the method of payment. Support for this view comes from an October 1993 comment from the securities analyst firm of Bear Stearns, which said that much of the induced demand from pharmaceutical insurance coverage for the Medicare population would be offset by pharmacy management programs, resulting in net revenue increases to the entire industry of \$1 billion to \$2 billion.

In addition, it is possible that the revenue realized by increased demand will be further offset by the rebate, resulting in a net negative financial impact. Indeed, independent securities analysts have already recognized this. A September 1993 report from Lehman Brothers, for example, asserts that "a 15% discount off this segment of drug sales [the proposed rebate amount has since increased to 17%] would completely negate the volume gains generated in the initial years, and in the out years, the pricing discounts would outweigh any volume gains."

Again, if a company must subject the revenues it receives from medicines developed for diseases of the elderly to a minimum 17% tax — a tax that could apply to more than 40% of its business — that company would have to ask itself whether it makes financial sense to invest the hundreds of millions of dollars and staff hours such a project requires.

Despite these and other provisions that would discourage investments in innovation, this does not mean the research-based pharmaceutical industry would end its research. Research is what we do. It defines us. It is central to our mission.

Despite these and other provisions that would discourage investments in innovation, this does not mean the research-based pharmaceutical industry would end its research. Research is what we do. It defines us. It is central to our mission. At the same time, we would not be blind to the environment in which we do our research. We would not be blind to the marketplace forces and economic realities that would determine our success and stability as a company. The ultimate effect, then, may well be a bias away from long-term, high-risk projects to shorter-term, lower-risk projects. The probable result would be a stream of new products that may not advance the pharmaceutical sciences significantly. They will be products representing incremental improvements and refinements in medicines in familiar therapeutic categories.

This is not to diminish the value of incremental gains, which are an important way science progresses. It is only to point out that in a highly regulated environment, the big stretch in R&D would be the exception rather than the rule. Only with incentives that reward high-risk ventures can pharmaceutical companies justify the sort of revolutionary research that may lead to wholesale changes in the way a disease is treated, for example, the search for a medicine that works at the genetic level to eradicate a disease as opposed to a palliative treatment that targets the symptoms of the disease.

My company, Glaxo, may provide a glimpse of how these forces would be translated into realities. Earlier, I talked about the success of one of our newer products, Zofran®, which has quickly become a standard therapy in oncology wards across the country.

Zofran® is the result of basic research into the role of the neurotransmitter serotonin that Glaxo began in 1972. It was not until 1990, when Zofran® was introduced into the market, that we were able to realize a return on our investment in research and development that spanned approximately 20 years. It is easy to forget the internal debates that occurred when the effort encountered seemingly insurmountable obstacles and the soul-searching discussions on whether to continue its funding. Given the significant difference the medicine is making in patients' lives, it seems almost unimaginable that anything could have sidetracked it. Yet we have to ask ourselves, if the project were beginning in an environment dominated by regulation and cost containment, would we pursue it? Fortunately I don't have to answer that question. Yet the fact remains, many similar questions are around the corner.

Some of those questions will be basic ones involving choice. Recently Glaxo announced a five-year \$15 million international research collaboration to find better treatments for tuberculosis. This initiative was launched because the company realized that although modern medicines and vaccines have done much to control the disease, TB remains a major health risk in much of the world. The new effort, in which Glaxo scientists will work with scientists from three academic institutions, will attempt to discover novel targets for new drugs, using the techniques of biochemistry, molecular biology and genetics.

In planning this venture, Glaxo had a choice: Should we invest in a therapeutic area in which well-defined drug regimens already exist? Should we be satisfied

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with existing therapy, or should we attempt to take the therapy to the next level? Our answers might have been different in an environment dominated by regulation and cost containment.

In another collaboration, Glaxo is investigating some exciting, promising yet futuristic work in anti-sense research, which involves blocking the genetic messages that actually cause disease. This research has a potential to one day prevent herpes, cancer, the common cold, and even AIDS. This is an area of science that has wondrous potential, yet it will be years — some say as many as 15 years or more — before we know whether we can successfully translate anti-sense research into medicines.

Again, our choice was clear: Do we embark on what is clearly a long-term, high-risk project? Or do we play it safe, investing in discovery efforts in which the research pathway and the possible product are more well-defined? While we are firmly committed to our anti-sense project, an environment in which our potential for return is limited would make these questions far more difficult.

Such an environment would force yet other, perhaps more fundamental choices as well. If the exigencies of a regulated marketplace and the realities of business cause investments in innovation to slow or shrink, which project gets the funding? Would it be the one offering hope to cancer patients whose vomiting is so severe that many choose to forego the chemotherapy treatments that may save their lives? Or would it be the one holding the potential to wipe out tuberculosis worldwide? Or would it be the one that might save thousands of lives otherwise lost to AIDS? Or would it be the one that might save billions of dollars of lost productivity costs associated with the common cold?

If society is to continue to realize the benefits of innovation, free market forces must be allowed to work. Market-based managed competition provides an excellent framework for reform, and may well be the solution we all are looking for. However, in a highly regulated setting such as the one proposed in the Administration's plan, we may see short-term cost-containment, but some very significant long-term costs.

What will those costs be? If the pharmaceutical industry must become more conservative in its R&D decision-making, what will be the costs to the thousands suffering from arthritis and osteoporosis? What will be the costs for thousands more Alzheimer's sufferers, diabetics and heart disease victims?

As a physician, a former hospital administrator and pharmaceutical CEO, I'm convinced the costs of curtailing pharmaceutical research — both in economic and human terms — would be tremendous. But how do we as an industry or we as a society quantify that cost? How do we count expenses associated with a medicine that might have been discovered, but wasn't?

We obviously cannot look into the future and find the answers. We can say with certainty, however, that we must not enact health care reforms that diminish the promise of continued biomedical innovation. For it is innovation that holds the key to lower medical costs, improved health, and better and longer lives for us all.



Mr. WAXMAN. MR. ENGMAN.

**STATEMENT OF LEWIS A. ENGMAN**

Mr. ENGMAN. Thank you, Mr. Chairman and members of the committee. My name is Lew Engman and I am the President of the Generic Pharmaceutical Industry Association, which represents the leading United States manufacturers and distributors of generic prescription medicines.

Let me begin by saying that a strong, competitive generic pharmaceutical industry is key to meaningful health care reform. One of the challenges of reform is to provide quality medical services to consumers as cost-effectively as we can. Medicines play a critical role in lowering health care costs. They can be an effective and economical way to treat illness without expensive surgery and hospitalization. And this, Mr. Chairman, is what the generic pharmaceutical industry is all about, providing quality medicines to consumers at the lowest cost.

The administration's proposed Health Security Act earns high marks for its appreciation of the importance of the role of generic medicines and for its efforts to maintain a vitally competitive generic drug industry:

It mandates coverage of prescription drugs in its comprehensive benefit package and in the expanded Medicare program for the elderly.

It covers only the cost of the generic drug for multi-source drugs unless a doctor affirms in writing that a brand is medically necessary.

It uses the competitively derived open market generic price as the basis for reimbursement.

Fifty-seven percent of Americans are without coverage to help pay the cost of vital medicines and for many of them, including some of our oldest and sickest citizens, this gap may mean a cruel choice between drug therapies and other necessities. When drugs are not purchased, the cost of that choice of not purchasing them may be more severe illnesses, more frequent use of expensive hospital and specialist services at public expense.

In any prescription reimbursement plan, the cost to the participant or the taxpayers depends on how well that plan controls its costs. There ordinarily is no medical reason to pay the higher price for a drug which is available in both brand and generic form. Thus, maximum utilization of generic drugs is central to lowering the costs of medical care.

In fact, I might point out that generic drugs are the only sector of the entire health care industry that has not only contained costs, but actually rolled costs back throughout the last 10 years of escalating health care costs. This is being achieved because price competition and market forces have been allowed to flourish within the generic drug industry, thanks to your leadership, Mr. Chairman, in securing passage of the historic 1984 Waxman-Hatch Act. That Act breathed new life into the pharmaceutical industry by reinvigorating competition.

Unfortunately, as you also know, Mr. Chairman, present laws hinder that competition and the growth of the generic drug industry with artificially imposed rebates. Rebates make absolutely no

sense at all for generic products, the prices of which are constantly under market pressure. Moreover, rebates imposed on generic drug suppliers by Medicaid since 1990, as well as by some states, actually have been counterproductive, having the opposite effect from that intended. Rebates penalize hardest the most competitive generic companies with the lowest profit margins. Ironically, rebate laws have the effect of reducing generic competition by inhibiting further price cutting among existing products and by discouraging new manufacturers from entering the market and joining the competitive fray.

The administration's proposed Health Security Act clearly recognizes this anticompetitive situation and works to correct the Medicaid rebate problem, thereby enhancing market forces and competition in the system to create further downward pressures on drug prices.

As Congress considers health care reform legislation, it needs to keep in mind the basic principle of providing prescription drug coverage at the least possible cost. Achieving that objective depends upon maintaining and strengthening a competitive generic drug industry that is free to compete aggressively in holding down the costs of prescription drugs. GPIA believes that we are part of the solution and we look forward to working with the members of this committee to meet that goal.

Thank you very much.

Mr. WAXMAN. Thank you, Mr. Engman.

[The prepared statement of Mr. Engman follows:]

STATEMENT  
OF  
LEWIS A. ENGMAN  
PRESIDENT  
GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

Good morning, Mr. Chairman and members of the Committee. My name is Lewis A. Engman and I am President of the Generic Pharmaceutical Industry Association. GPIA represents the leading United States manufacturers and distributors of generic prescription medicines. Thank you for the opportunity to present our perspective on health care reform this morning.

A strong, competitive generic pharmaceutical industry is key to meaningful health care reform. One of the challenges of reform is to provide quality medical services to consumers as cost-effectively as possible. Medicines play a critical role in lowering health care costs. They can be an effective and economical way to treat illness without expensive surgery and hospitalization. And this, Mr. Chairman, is what the generic pharmaceutical industry is all about -- providing quality medicines to consumers at the lowest cost.

The Administration's proposed Health Security Act earns high marks for its appreciation of the importance of the role of generic medicines and for its efforts to maintain a vitally competitive generic drug industry:

- it mandates coverage of prescription drugs in its comprehensive benefit package and in the expanded Medicare program for the elderly;
- it limits its coverage to medically necessary goods and services;
- it covers only the cost of the generic drug for multi-source drugs unless a doctor affirms in writing that a brand is medically necessary, and it provides for advance authorization and after-the-fact review of such prescriptions;
- it provides for public education on the advantages of generic drugs;

- it uses the competitively derived open market generic price as the basis for reimbursement; and
- it uses the generic price as the basis for computing deductibles and self-pay limits.

Although some private and public health insurance programs, such as the Medicaid program, include prescription drug coverage, many private plans and the Medicare program do not cover outpatient prescription drug costs. In addition, millions of Americans have no health insurance at all. Thus, 57 percent of Americans are without coverage to help pay the cost of vital medicines. For many, including some of our oldest and sickest citizens (among whom 64 percent have no drug coverage until they are hospitalized), this gap may mean a cruel choice between drug therapies and other necessities. And, when drugs are not purchased, the cost of that choice may be more severe illnesses and more frequent use of expensive hospital and specialist services at public expense.

In any prescription reimbursement plan, the cost to the participant or the taxpayers depends on how well the plan controls its costs. Government approved generic medicines are available to patients at prices as much as two to ten times less than the same medicine contained in brand versions. There ordinarily is no medical reason to pay the higher price for a drug which is available in both brand and generic form. Thus, maximum utilization of generic drugs is central to lowering the costs of medical care.

In fact, generic drugs are the only sector of the entire health care industry that has not only contained costs, but actually rolled costs back



throughout the last ten years of escalating health care costs. This is being achieved because price competition and market forces have been allowed to flourish within the generic drug industry -- thanks to your leadership, Mr. Chairman, in securing passage of the historic 1984 Waxman-Hatch compromise, the Drug Price Competition and Patent Term Restoration Act. That Act breathed new life into the pharmaceutical industry by re-invigorating competition. The competition cycle is such that once the brand name drug comes off patent, at least one generic version comes to market at a lower price. Moreover, as additional generic manufacturers' versions of the product come to market, they compete vigorously with each other and this competition forces prices even lower. American consumers benefit.

GPIA believes that achieving the goals of meaningful health care reform -- access and reasonable cost -- must include a universal drug benefit because medicines save lives and money, reducing the need for much surgery and hospitalization. In order to extend this drug benefit at increasingly lower cost to those Americans currently uncovered, it is essential to enhance the competitive vitality of the generic drug marketplace.

Unfortunately, as you know, Mr. Chairman, present laws hinder that competition and the growth of the generic drug industry with artificially imposed rebates. Rebates are superfluous and make no sense for generic products, the prices of which are constantly under market pressure. Moreover, rebates imposed on generic drug suppliers by Medicaid since 1990, as well as by some states, actually have been counterproductive, having the opposite effect from that intended. Rebates penalize hardest the most competitive generic companies with the lowest profit margins. Ironically, rebate laws have the effect

of reducing generic competition by inhibiting further price cutting among existing products and discouraging new manufacturers from entering the market and joining the competitive fray.

The Administration's proposed Health Security Act clearly recognizes this anti-competitive situation and corrects the Medicaid rebate problem, thereby enhancing market forces and competition in the system to create further downward pressures on drug prices.

As Congress considers health care reform legislation, it needs to keep in mind the basic principle of providing prescription drug coverage at the least possible cost. Achieving that objective depends upon maintaining and strengthening a competitive generic drug industry that is free to compete aggressively in holding down the costs of prescription drugs. GPIA believes that we are part of the solution and we look forward to working with you to meet that goal.

Mr. WAXMAN. I want to commend this panel. You have given us excellent testimony and considerations that we have to look at very, very carefully as we design any kind of reform.

For the record, let me ask each of you this. Do you all agree that we ought to include in a health care reform plan coverage for prescription drugs as a benefit both as part of the standard benefit package and as part of Medicare?

Dr. Vagelos.

Mr. VAGELOS. Yes, indeed I do.

Mr. WAXMAN. Mr. Raab.

Mr. RAAB. Yes.

Mr. WAXMAN. Dr. Sanders.

Mr. SANDERS. Yes.

Mr. WAXMAN. Mr. Engman.

Mr. ENGMAN. They are cost-effective, they save lives and money. Yes.

Mr. WAXMAN. Mr. Mossinghoff.

Mr. MOSSINGHOFF. Yes, sir.

Mr. WAXMAN. Dr. Vagelos and Dr. Sanders and Mr. Raab, I want to ask you about these extremely expensive breakthrough drugs. I hear what you are saying about the valuable research that your companies have done and I applaud you for the important drugs that your companies have discovered. In the past you've had wide latitude as to what price you would charge for breakthrough drugs. But since most drugs were paid for by patients or by private insurance, you had to consider the possibility that the patient could not afford the drug or the insurance companies would change their policies so as not to reimburse for your drugs. This constraint may have kept most drugs under \$10,000. Under health care reform you will have a guaranteed market outside of Medicare. You have a guarantee that the health plans will purchase your breakthrough drugs regardless of their price. What will keep you from charging \$20,000, \$30,000, \$50,000 or more for these drugs?

Dr. Vagelos.

Mr. VAGELOS. First of all, I don't like the definition of breakthrough drugs as it has been implied in this group. I consider, for instance, Zofran a breakthrough drug; I consider Proscar a breakthrough drug. I don't think every breakthrough drug costs \$10,000. Some incredibly important drugs cost a couple hundred dollars or \$500 a year and do incredible things. So I think we ought to change that implication.

Second, the size of the market with the Health Security Act. There have been at least two studies that I know of, the Lewin-VHI study and another study done by Don Muse, which indicate that there will be an overall reduction in revenues of something between 6 and 11 percent with the total program.

The issue of some group to determine the reasonableness of prices of breakthrough drugs is very difficult to deal with simply because the definitions of breakthrough drugs are difficult to start with, and second, there are very few of them that are, I would say, clearly priced very high in terms of people's views today, and therefore, to set up an organization that would oversee all breakthrough drugs would be cumbersome, difficult, and it would put a shadow on the—

Mr. WAXMAN. I know you are against it, but how do you answer the question, how do we in some way get some kind of reasonable pricing on these drugs? What alternative would you have for us to consider, and are we simply going to, however you define these breakthrough drugs, pay these incredible amounts of money and just leave it to the drug companies to decide what the price will be?

Mr. VAGELOS. I think as we look historically there are so few of them that it's not a major issue. I think someone used a number which was a very small percent of the total drugs. I would say that the competitiveness of the industry today is such that any breakthrough is followed by a number two or number three within 3 or 4 years. Rather than encumber the system and put a shadow over all those companies that are attempting to start long-term research and invest hundreds of millions of dollars who would be at risk in having a third party decide whether their price will be considered reasonable, I would just wait for the free market and market forces to take care of those outliers that might occur.

Mr. SANDERS. I agree with Dr. Vagelos, Mr. Chairman. I think what we are dealing with is a few very high profile examples of drugs that cost an extraordinary and almost inconceivable amount of money. What we are talking about is a \$900 billion, I guess a trillion dollar health care system, with 1/500 of that health care system being allocated to the definition of breakthrough drugs, most of which are well under the \$1,000 a year cost. Zofran is one example. That's about \$130 a treatment. That is maybe 10 percent of the total cost of chemotherapy. It's very affordable and shortens hospital stay. Very cost-effective. Emitrex, our migraine drug, is another breakthrough drug. It's the first treatment of migraine that has been introduced in over 30 years, and it is an acceptable cost. It may be \$50 to \$75 per migraine episode, but think of the countless days that are saved in terms of productive work and quality of life.

So I would say that the marketplace will correct this. It already is, as I said in my testimony. When I was director of the Massachusetts General Hospital back in 1972 to 1981, I went through the Nixon economic stabilization program and the Jimmy Carter program. None of those programs were associated with any change in the industry, so it was not surprising that there was a pop-up effect when the price controls came off.

What we are dealing with now is a fundamental structural change in the health care delivery system in the United States, and the marketplace is working. It ain't perfect, but it is working and it will continue to be very effective.

Mr. WAXMAN. Are you describing the status quo or are you talking about the health care reform?

Mr. SANDERS. I'm talking about health care reform. Well, I'm talking about what is happening in the marketplace. It's not exactly a status quo. It's moving pretty fast in terms of the restructuring of these companies. Health care reform is very important in terms of getting people into the system that are outside of the system right now. I think if we follow a market-based reform system, then we are going to realize the goals we all share in terms of health care delivery in this country.



Mr. WAXMAN. My only comment to you would be that we have 39 million uninsured now and I think we are adding many, many more to that number as health care costs go up and companies can't afford to provide that benefit to their employees. That doesn't counter what you are saying, that there are changes in the market that seem to be working well to contain some costs. You agree we need a health care reform bill to move things along?

Mr. SANDERS. Yes, sir. We need access.

Mr. WAXMAN. Mr. Raab.

Mr. RAAB. Yes, sir. I would like to make a couple of points. It sort of goes back to the goal of providing quality care and obviously containing costs, which are the sum and net of all of our goals for reform of health care today and in the future.

I would point out in my company, which has sold in its 18-year history \$2.6 billion worth of products, we have spent \$1.6 billion in research and development—these are cumulative numbers—and our cumulative loss has been \$200 million in our history.

One of our products, interferon gamma, is for 400 people; Protopin, our first growth hormone, is for around 12,000 children; our second growth hormone for chronic renal insufficiency, Neutropin, is for 3,000 patients; Pulmozyme is for about 20,000, we think, treatable patients in the United States with cystic fibrosis; and even TPA, which is used for heart attacks, total is treating less than 150,000 patients.

So we are working fundamentally for small patient populations, particularly in biotechnology. There are two reasons, interestingly. One, virtually all of our products are injectables. There is a reason for that. Large molecules are not absorbed. So everything we work on is for injection.

Second, a biological product is very expensive to produce.

I have often thought about this as I have pondered health care reform since the three of us actually were in Little Rock for the President's Economic Conference before he was inaugurated and began to think about the impacts of what was being discussed for health care reform.

I think of myself, and I refer also to what Dr. Vagelos said, when I sat in my office in south San Francisco, a little north of your district, and Steve Shack came into me, a pulmonologist, a molecular biologist that works for us, and he decided to go around our committee structure and come right to the CEO and say, I want to develop this drug for cystic fibrosis. He described his idea for me that he had gotten from a product that was bovine-based, that Merck had done many, many years before, that was not as pure and helpful in the patients. I ignored, which you can do in private industry, the committee's methods and I said let's go for it.

I don't know, and I thank God I'll never have to find out, what I would have done if I had thought I was going to have to come to Washington last December when it was approved in less than 6 years, which is pretty unusual, from idea to marketplace and appear before 6, 5, 20 wise people to discuss the proper price for this breakthrough drug.

I don't know what decision I would make, but I personally believe, and I believe this with a passion—like all of us sitting here, we have spent our lives in this industry and are very proud of it—

I believe it would have been a very difficult decision for me and for my board of directors and for my shareholders, and I might not have done it. As I said in my testimony, I don't think anything that we do in health care reform should inhibit, discourage the drive and innovation, whether it's little companies or giant companies, to find these solutions that we are working on and spending so much money on.

Mr. WAXMAN. Thank you very much for your answer.

Mr. Bliley.

Mr. BLILEY. Thank you, Mr. Chairman.

Dr. Vagelos, it has been said that pharmaceuticals "sell themselves." Why, then, do you have to spend so much money on promotion?

Mr. VAGELOS. Thanks, Mr. Bliley. Good question.

Mr. BLILEY. That's what the First Lady said to me when I asked her about costs on September 28. She said she would get me the answer. Five months later I'm still waiting. I hope you don't keep me waiting that long.

Mr. VAGELOS. No. I'm going to tell you right now the answer.

The promotion is indeed expensive, and the reason for that is that in our so-called promotion we have to educate physicians, and especially when we introduce new products.

I have posted up there and we can distribute copies of what is a circular that goes into the package of Vasotec, one of our important drugs. What that indicates is a very complex series of studies, the results of many, many years of studies that demonstrate the effectiveness, the safety, all the potential complications and all the science that has gone into the study of the disease and the study of the drug. By law, we have to transmit this information to the physicians. It's the job of our representatives, who are trained at least 6 weeks each year, to learn this material and to transmit it and to get it out to people.

It is an incredibly important thing to be able to get the information across and it is most difficult when you are introducing a drug in an area wherein there has been no previous therapy, such as the one I mentioned earlier, Proscar for treatment of benign prostate enlargement. Doctors did not know how to make the diagnosis. There had never been a drug in the area, and therefore we had to go and teach the doctors how to diagnose the disease, which was normally not even discussed with patients, and then teach them about the drug. It's an incredibly important project for us and it's very expensive to do that.

I would like to send around a little pamphlet, and I would ask, Mr. Chairman, whether we can have this distributed to your subcommittee. It demonstrates what is required by law.

Mr. BLILEY. Mr. Chairman, I ask unanimous consent to include the pamphlet in the record.

Mr. WAXMAN. Without objection, we will receive this for the record.

[The document follows:]

# Measles, Mumps, and Rubella

## What You Need to Know



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
Public Health Service  
Centers for Disease Control  
Atlanta, Georgia 30333



### For Clinic/Office Use

Clinic/Office Address: \_\_\_\_\_

Date Vaccine Administered: \_\_\_\_\_

Vaccine Manufacturer: \_\_\_\_\_

Vaccine Lot Number: \_\_\_\_\_

Site of Injection: \_\_\_\_\_

Signature of Vaccine Administrator: \_\_\_\_\_

Title of Vaccine Administrator: \_\_\_\_\_

## Please read this pamphlet before you or your child gets a vaccine!

Before vaccines were available to protect against measles, mumps, and rubella, nearly everyone caught these diseases while growing up. The use of vaccines against these diseases has greatly reduced the number of people getting these illnesses.

The benefits of the vaccines to prevent these diseases are greater than the possible risks for almost all people. A person who receives vaccines benefits from the protection they provide. When many people are vaccinated, everyone benefits because the chance for spread of disease is reduced.

Serious health problems are caused by these diseases. Therefore, it is important to be protected by the vaccines. Usually, vaccines for all 3 diseases are combined and are given together as 1 shot, called the **MMR** vaccine. Usually it is given 2 times, first at 15 months of age and again before school entry (4 to 6 years of age), or before entering middle school or junior high school.

Every vaccine and medicine has both benefits and risks. Most problems that occur after vaccines are mild, but a few people may have a serious problem. While most people should get MMR, a few people should not, and a few others should delay getting the vaccine.

This pamphlet tells you more about:

The diseases measles, mumps, and rubella	pages 1 & 2
The benefits of the vaccines	page 2
The risks of the vaccines	pages 3 & 4
When your child should routinely get vaccines	page 5
When the vaccines should be delayed or not be given	page 6
What to look for and to do after the shot	pages 7 & 8

## WHAT ARE THESE DISEASES?

**MEASLES** is a serious disease. It is very easily passed from one person to another. It causes a high fever, cough, and a rash and lasts for 1 to 2 weeks. In recent years, 3,000 to 28,000 cases of measles have been reported yearly in the United States and outbreaks still occur. One out of every 10 children who catch measles will also have an ear infection or pneumonia.

Measles can also cause an infection of the brain that could lead to convulsions (seizures, fits, spasms, twitching, jerking, or staring spells), hearing loss, and mental retardation. This happens to about 1 out of every 1,000 children reported to have the disease. In the United States, 1 child out of every 500 to 10,000 who gets measles dies from it.

Babies and adults who catch measles are often much sicker and are more likely to suffer longer or die than elementary school children and teenagers with measles.

**MUMPS** causes fever, headache, and swollen, painful glands under the jaw. Mumps sometimes can be a very serious disease. It lasts for several days and it is easily passed from person to person. In recent years, 4,500 to 13,000 cases of mumps have been reported each year in the United States and outbreaks still occur.

Mumps can cause a mild inflammation of the coverings of the brain and spinal cord (meningitis) in about 1 person in every 10 who get it. Swelling or inflammation of the brain is reported in about 1 case out of every 200. Before there was a mumps vaccine, many children had hearing loss caused by mumps. About 1 out of every 4 teenage or adult males with mumps will have a painful swelling of the testicles for several days. This usually does not make the person unable to father children.

Teenagers and adults, especially males, who catch mumps are often much sicker and more likely to suffer longer than children do.



## WHAT ARE THE RISKS OF THESE VACCINES?

Most people who get the MMR vaccine will not have a problem. Others will have minor problems, such as a sore or red arm that lasts for 1 to 2 days. Rarely, a person may have a serious problem.

If you or your child receives the MMR, there is a chance that any of the problems listed below could happen. If problems occur, they almost always happen after the first shot. If you or your child receives only the measles vaccine, or the mumps vaccine, or the rubella vaccine, you should only look for the problems listed for the vaccine received.

### *Mild or Moderate Problems From the Vaccines*

#### MEASLES VACCINE:

- A rash may occur from 1 to 2 weeks after receiving the measles vaccine. About 5 children out of every 100 will get a rash.
- A fever of 103°F or higher after receiving the first shot of measles vaccine, even though the child may not act sick. About 5 to 15 young children out of every 100 who receive the vaccine get such a fever. This could happen from 1 to 2 weeks after receiving the vaccine and usually lasts 1 or 2 days. The fever occurs less often after a second shot.

#### MUMPS VACCINE:

- A little swelling of the glands in the cheeks and under the jaw that lasts for a few days. This could happen from 1 to 2 weeks after getting the mumps vaccine. This happens rarely.

#### RUBELLA VACCINE:

- Swelling of the lymph glands in the neck or a rash that lasts 1 or 2 days. This could happen 1 to 2 weeks after getting the rubella vaccine in about 1 child out of every 7 who get the vaccine.
- Mild pain or stiffness in the joints that may last up to 3 days. This could happen from 1 to 3 weeks after getting the shot. This problem happens to about 1 child out of every 100 who get the shot and to about 25 adults out of every 100. Women have this problem more than men and it may happen in up to 40 women out of every 100. Rarely, pain or stiffness can last for months or longer and can come and go.

**RUBELLA** is also called German measles. In recent years, only a few hundred cases of rubella were reported each year. It is usually a mild disease that lasts for a short time. **BUT if a pregnant woman catches the disease**, rubella is very dangerous to her unborn baby. Up to half of the women who catch rubella when they are pregnant will lose their babies or have babies born with heart disease, or babies who will be blind or deaf, or who have problems with learning. In the United States, before there was a rubella vaccine, many thousands of babies with these serious health problems were born to mothers who caught rubella while they were pregnant.

People who catch rubella usually have mild fever, swollen glands in the neck, and a rash that lasts up to 3 days. Rubella may cause soreness in the joints and swelling of the joints (arthritis). This may happen in up to 70 out of every 100 women. Usually this lasts only for a week or two but in rare cases it may last for months or years, or may come and go.

People who do not get the rubella vaccine are in danger of catching rubella and passing it on to a pregnant woman. About 1 out of every 10 women in the United States is not protected against rubella.

## WHAT ABOUT THE VACCINES AND THEIR BENEFITS?

The vaccines to protect against all 3 diseases are usually given together in 1 shot, called the MMR vaccine. One MMR shot protects 90 to 98 people out of every 100 against **measles, mumps, and rubella** if they get the vaccine at the right age. Usually a child gets the first MMR at 15 months of age, but sometimes it should be given at 12 months of age, or even earlier during an outbreak. To protect the few children not protected by the first MMR, a second MMR is recommended when a child enters school for the first time or when a child enters middle school or junior high school.

These vaccines protect nearly all people for a very long time, probably for life. However, if an outbreak of measles occurs, doctors may recommend a second MMR shot. Teenagers and adults who do not know if they are protected against these diseases should ask their doctor or clinic about getting the MMR.

- Painful swelling of the joints (arthritis) happens to fewer than 1 child out of every 100 who get the rubella vaccine. About 10 adults out of every 100 can also have this problem, which usually lasts a few days to a week. Rarely, this swelling has been reported to last longer, or to come and go. Damage to the joints is very rare.

- Pain or numbness, or "pins and needles" feeling in the hands and feet that lasts for a short time. This happens rarely.

#### More Serious Problems From These Vaccines

- Children 6 months through 6 years of age who get the vaccines can, in rare cases, have a brief convulsion (fits, seizures, spasms, twitching, jerking, or staring spells). This usually occurs 1 to 2 weeks later, and usually comes from the fever caused by the measles vaccine. Very rarely, hearing loss has been reported, but it is not known whether hearing loss is ever caused by these vaccines. Very rarely, a person can have inflammation of the brain after receiving the vaccine. This usually clears up completely. These brain problems have been reported to happen about 1 time for every million MMR shots given.

- There is a rare chance that other serious problems and even death could occur after getting the vaccines. Such problems could happen after taking any medicine or after receiving any vaccine.

#### ARE THE BENEFITS OF THE VACCINES GREATER THAN THE RISKS?

Yes, for almost all people.

These diseases make some people very ill. Almost all people who get the vaccines are protected from these diseases. A small number of people have problems after getting the vaccines. The problems that may happen after receiving the vaccine occur much less often than when a person has the disease.

Experts believe that most people should receive these vaccines. After reading this pamphlet and talking with your doctor or nurse, you can decide whether there is any reason for you or your child to delay getting or not get the vaccine.

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#### WHEN SHOULD YOUR CHILD GET THE MMR VACCINES AND OTHER VACCINES?

Below are all of the vaccines that most infants and children should get and the age when most experts suggest they should get each dose of vaccine.

RECOMMENDED SCHEDULE OF VACCINATIONS FOR ALL CHILDREN						
Vaccine	2 Months	4 Months	6 Months	12 Months	15 Months	4-6 Years (Before School Entry)
DTP	DTP	DTP	DTP	DTP	DTP <sup>2</sup>	DTP
POLIO		POLIO	POLIO		POLIO <sup>3</sup>	POLIO
MMR					MMR <sup>1</sup>	MMR <sup>1</sup>
HIB		HIB	HIB	HIB		
Option 1 <sup>4</sup>		HIB	HIB	HIB		
Option 2 <sup>5</sup>		HIB	HIB			
Vaccine	Birth	1-2 Months	4 Months	6-18 Months		
HB						
Option 1	HB	HB <sup>†</sup>			HB <sup>‡</sup>	
Option 2		HB <sup>‡</sup>	HB <sup>‡</sup>		HB <sup>‡</sup>	

DTP: Diphtheria, Tetanus, and Pertussis Vaccine  
 Polio: Live Oral Polio Vaccine drops (OPV) or Killed (Inactivated) Polio Vaccine shots (IPV)  
 MMR: Measles, Mumps, and Rubella Vaccine  
 HIB: *Haemophilus b* Conjugate Vaccine  
 HB: Hepatitis B Vaccine

\* Many experts recommend these vaccines at 18 months.

† In some areas this dose of MMR vaccine may be given at 12 months.

‡ Many experts recommend this dose of MMR vaccine be given at entry to middle school or junior high school.

§ HIB vaccine is given in either a 4-dose schedule (1) or a 3-dose schedule (2), depending on the type of vaccine used.

‡ Hepatitis B vaccine can be given simultaneously with DTP, Polio, MMR, and *Haemophilus b* Conjugate Vaccine at the same visit.

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### WHEN SHOULD THE VACCINES BE DELAYED OR NOT BE GIVEN?

There are several reasons some people may need to delay getting the MMR vaccine or not get the shot at all. These reasons also apply to measles vaccine, mumps vaccine, and rubella vaccine.

Tell the doctor or nurse if the person who is going to get the vaccine:

- Is sick with something more serious than a minor illness such as a common cold. Delay the vaccination until the person is better.
- Has ever had an allergy problem after eating eggs that was serious enough to require the attention of a doctor. This does not matter if the person is only receiving the rubella vaccine.
- Has had an allergy problem to an antibiotic called neomycin so serious that it required treatment by a doctor.
- Is born with or develops any disease that makes it hard for the body to fight infection, such as cancer, leukemia, lymphoma (cancer of the lymph glands).
- Is taking special cancer treatments such as x-rays or drugs, or is taking other drugs such as prednisone or steroids that make it hard for the body to fight infection.
- Has received gamma globulin during the past 3 months.
- Is pregnant or thinks she is pregnant.

All people who do not get the vaccine because of one of the reasons listed above should check again with the doctor or nurse about getting the vaccines at a later time.

### SHOULD PREGNANT WOMEN RECEIVE THE VACCINES?

Women who are pregnant, who think they are pregnant, or who might get pregnant in the next 3 months, should not get MMR or other vaccines for measles, mumps, or rubella. This is recommended even though these vaccines are not known to cause problems for pregnant women or their unborn babies. It is safe, however, to give a shot to a child whose mother is pregnant.

If a woman is pregnant and does not know if she is protected against rubella, she should tell her doctor. A woman who receives any of these vaccines should not get pregnant for the next 3 months.

A woman who needs protection against any of these diseases should be given the vaccines right after her baby is born.

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### WHICH PEOPLE MAY BE MORE LIKELY TO HAVE A CONVULSION AFTER RECEIVING MMR?

The chance of a child having a convulsion with fever after receiving measles vaccine is small. However, the risk is up to 5 times greater if the child has ever had a convulsion before. It is also greater if the child's brother, sister, or parent has ever had a convulsion.

Most experts agree that people who have had a convulsion should still get the MMR vaccine. Also, people who have a family member who has had a convulsion should get the MMR vaccine.

The overall chance of convulsion after getting the vaccine is still rare. It is usually the fever that causes the convulsion. Most experts believe that convulsions with fever do not cause any permanent damage to the child.

Be sure to tell the doctor or nurse who is giving the shot about any history of convulsions. Talk with them about medicines or other ways you can reduce fever from the shot.

If there was a problem after receiving the first MMR or separate shots for measles, mumps, or rubella, be sure to tell the doctor or nurse before receiving a second shot of the vaccine.

### WHAT TO LOOK FOR AND TO DO AFTER THE SHOT

Talk with the doctor or nurse who gives the shot about medicines or other ways you can treat fever from the vaccine.

This pamphlet lists the problems (on pages 3, 4, 6, and 7) that may occur after receiving MMR or other shots for measles, mumps, or rubella.

As with any serious medical problem, if the person has a serious or unusual problem after getting the vaccine, **CALL A DOCTOR OR GET THE PERSON TO A DOCTOR PROMPTLY.**

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**WHAT VACCINES DOES YOUR STATE REQUIRE?**

To protect as many children as possible from these diseases, all states require certain vaccines before the child goes to child care or school. Ask your doctor or nurse what vaccines your state requires.

Department of Health and  
Human Services  
Public Health Service  
Centers for Disease Control  
MMR 10/15/91

**VACCINE ADMINISTRATION RECORD**

The doctor or clinic may keep this record in your medical file or your child's medical file. They will record what vaccine was given, when the vaccine was given, the name of the company that made the vaccine, the vaccine's special lot number, the signature and title of the person who gave the vaccine, and the address where the vaccine was given.

"I have read or have had explained to me the information in this pamphlet about measles, mumps, and rubella diseases and MMR, Measles-Rubella, Measles, Mumps, and Rubella vaccines. I have had a chance to ask questions that were answered to my satisfaction. I believe I understand the benefits and risks of the MMR, measles, mumps, and rubella vaccines and ask that the vaccine checked below be given to me or to the person named below for whom I am authorized to make this request."

Vaccine to be given: MMR ☐ Measles and Rubella ☐ Measles ☐ Mumps ☐ Rubella ☐

Information about person to receive vaccine (Please print.)					
Name:	Last	First	Middle Initial	Birthdate	Age
Address:	Street	City	County	State	Zip
Signature of person to receive vaccine or person authorized to make the request (parent or guardian):					
X _____				Date: _____	

MMR 10/15/91

Mr. VAGELOS. Thank you.

This is simply a piece of literature that doctors must distribute to the parents of children who are going to be immunized. You will note that it has all the information for parents on immunization. We publish that; we print that, although it is required by government, at a cost of about \$1.5 million per year. If you will notice, we don't have a Merck name on the pamphlet. It has HHS as the source of the pamphlet. So we believe deeply that that promotion for us is education and part of our job is not only discovering and making the drug, but educating doctors so that they can use it properly.

Mr. BLILEY. Could you explain the different roles of the National Institutes of Health and the pharmaceutical industry in discovering and developing new medicines?

Mr. VAGELOS. Yes. I'd love to, because I've spent part of my career in both places. The NIH is a great institution that produces wonderful pure basic research for the most part. They also do some applied research. But their great strength since 1950, when they started to grow so rapidly, is in production of basic information which can be picked up by various companies, commercial organizations that have applied research laboratories.

The strength of NIH is in discovery of new information relating to disease or mechanisms that can be applied to discovery of new drugs. The strength of the pharmaceutical industry is in applied research, taking that information and putting together biologists and many, many chemists to work on it for many years to try to make a drug.

The two groups interrelate very well and they know their jobs, they do their jobs very well. It has given the United States the strongest industry and the strongest national basic research unit in the world and it has given us an industry which is able to export and have a positive trade balance and support an enormously strong high tech industry.

Mr. WAXMAN. Thank you, Mr. Bliley.

Mr. Wyden.

Mr. WYDEN. Thank you, Mr. Chairman.

This has been an excellent panel. Let me start with you, Dr. Sanders. I too think that markets work when they operate on a good engine of information, good comparative information in particular. The problem is my sense is we are not getting enough of that good comparative information. I hear at home, for example, from HMO's and from constituents. They can't tell when a new product is going to be cheaper or more clinically effective. Dr. Lee said in his written testimony this morning that we are not getting enough. The advocates for the kids and the senior citizens on the last panel said we are not getting enough. It seems to me that it is very clear government does not have enough dollars to determine clinical effectiveness, let alone even get into these issues of costs.

My question to you, Dr. Sanders, is, what would make it more attractive to the private sector to bring the kind of information to the government during those initial visits on new products that would allow the government to get into this question of clinical effectiveness and cost-effectiveness?

Mr. SANDERS. Thank you, Congressman. I think that, as others have noted, there is a lot of activity already going on about studies of cost-effectiveness as we bring drugs to the market, but it's an ongoing question and a very important issue for the consumer and the patient to the extent that I think we could join in partnership with the government to develop studies. You could follow, for example, the study section modeled the National Institutes of Health. I personally would not favor giving the FDA additional responsibility of this particular point of view. It's really outside of their purview in terms of cost-effectiveness. Their main mission is safety and efficacy.

If there could be a structure which could be devised to the mutual satisfaction of industry and the government that would employ a public-private partnership, then there might be considerable merit in it.

I think that the benefit, therefore, would be by developing information relating to cost-effectiveness and quality and the trade-offs therefor between the two, and you would really obviate the need for a drug price review board. You would have all that information available disseminated by the government and the consumer and the buyer. Caveat emptor is the way we work in this system.

Mr. WYDEN. Let me ask about that. In my proposal I'm looking at a variety of incentives, for example, for drug companies to bring the kind of information I'm talking about to the government. I think, for example, we could give it out over an electronic bulletin board so that HMO's and insurance companies could get it. I would like to see it be used in conjunction with this matter of marketing claims, which has been certainly an issue important to the companies.

On this matter of the drug review board, what would you think about the idea of saying that companies that bring the cost-effectiveness and clinical effectiveness data to the government would be exempt from the price review board? That way we would be talking about something that would be in the public interest. The people that I talk to want to know whether these products are more cost-effective and clinically effective. You all have made it very clear to the chairman that you aren't holding a lot of rallies for the drug price review board. Why don't we say if you earn it through giving us good, objective, verifiable data, maybe we say you're exempt from the price review board? What would you think of that?

Mr. SANDERS. I think that's a very intriguing suggestion. We would like to work with you on it.

Mr. WYDEN. Mr. Chairman, I yield back.

Mr. WAXMAN. Thank you, Mr. Wyden.

Mr. McMillan.

Mr. MCMILLAN. We had some testimony earlier from Ken Abramowitz having to do with the availability of venture capital if we end up with a system of price controls that are envisioned in the Clinton plan. I think that has two applications, as I brought out earlier.

Number one, the insurance industry, in order to underwrite the expansion of insured plans, is going to have to dramatically expand its capital base, I think we had some testimony, as much as \$90 billion in order to provide the reserves to do that. Of course you

operate in an area of free enterprise supplying product to the industry, perhaps in some cases dependent upon venture capital, particularly the new enterprises. As you read the proposal, what do you think the effect will be upon the capacity of the private sector to provide the investment capital necessary to engender and carry out a competitive response?

Mr. RAAB. I think it's certainly a very fundamental issue and question to all industry, but particularly the biotechnology and the smaller companies. I do have a report from Ernst & Young which has explained what has happened to raising funds in the biotechnology industry that I think would be of interest to the committee. It was issued on February 7. It would give more details, if we can pass that out to the committee.

Mr. MCMILLAN. Mr. Chairman, can we make that information a part of the record?

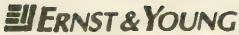
Mr. WAXMAN. Without objection, we will receive this for the record.

Mr. MCMILLAN. Thank you.

[Testimony resumes on p. 718.]

[The information follows:]





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Palo Alto, California 94304

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Kenneth B. Lee, Jr.  
National Director of  
Life Sciences Practice

February 7, 1994

Mr. Carl Feldbaum  
Biotechnology Industry Organization  
1625 K Street, N.W., Suite 1100  
Washington, DC 20006-1604

Dear Carl:

You have asked for our analysis of the strength and nature of the capital markets for biotechnology companies in 1993 and entering 1994. Following are some of my observations on offering activity in the biotechnology industry in recent years.

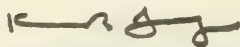
We issued a press release in January stating that the industry raised 21% more capital this year in the aggregate than last. If one only looks at these aggregated capital totals, one might conclude that the markets for biotechnology companies are recovering and healthy. For most biotechnology companies, particularly smaller ones, this would be an inaccurate conclusion. Consider the following:

- Since a mere few companies are profitable, biotechnology companies finance spending through stock offerings (both public and private). Expense increases are outpacing companies' ability to raise capital. Overall industry losses grew \$1.9 billion to \$3.6 billion as reported in Biotechnology '94. In addition, the industry spent about \$1.1 billion on capital additions. This results from, among other things, the increasing burn rates experienced by companies as they go further into clinical trials. Based on the growing number of biologicals in advanced clinicals, I expect an increase in future losses and capital spending.
- There are more companies and more public companies in 1993. We reported on a total of 1,231 companies (225 public) in Biotech '93 as compared to 1,272 companies (235 public) in Biotech '94. The size of the average IPO and follow-on offering declined from \$24 million in 1992 to \$20 million in 1993.

- There were several large, one-time financings by top-tier companies in 1993 which are not generally characteristic of most biotechnology companies. Chiron completed a \$200 million debt offering (there was no such offering in 1992). ALZA's spin-out of Therapeutic Discovery Corporation is counted as a 1993 financing of \$250 million, although this was not funded by the capital markets. ALZA also completed a \$270 million debt financing in 1993. Without this approximate \$700 million in 1993 financings, 1993 fund-raising would have been flat, compared to 1992.
- The average "survival index" (the number of months until a company runs out of cash) shrinks from 44 months to 28 months when the 10 largest companies are removed from the calculations (see attachment).
- During the industry's history, the largest percentage of capital provided has come from public capital markets, and it is unlikely that the industry can sustain financing increases without healthy public capital markets. Financings from public capital markets (both IPO's and follow-ons) have been on the decline since 1991, when approximately \$5 billion was raised. Based on our data, slightly over \$1.5 billion from public offerings was raised in 1992 and slightly less than \$1.5 billion from public offerings was raised in 1993.
- Public financings have been increasingly difficult to consummate. Many deals are reducing the asking price and number of shares at the "effective date," due to the soft market.
- Most public companies are trading below their January 1, 1993 price. Attached is a report published late in December by BioWorld giving stock price comparisons with January 1, 1993.
- One interesting financing phenomenon in 1993 was the emergence of the so-called PIPE financing (Private Investment in Public Enterprise). Approximately \$350 million of such financings were accomplished in 1993 (virtually none in 1992). Such transactions were generally pursued by biotechnology CEOs in 1993 due to lack of an alternative. In order to accomplish a PIPE financing, a company generally offers its shares at a discount to market (a market that is already at a depressed point) to private investors. If the biotechnology industry is forced to finance at a discount (off an already-depressed market price), the cost of the capital is thereby increased, potentially eliminating venture capitalists from early investments that are necessary to keep the pipeline of companies healthy. While the CEOs have little choice but to finance at these values, the volume of PIPE transactions suggests overall weakness in availability of capital from the general public.

To conclude, despite the fact that several unique offerings and the emergence of PIPE transactions effectively skewed the 1993 financing statistics, it is widely believed in the industry that the biotechnology industry's financing needs far exceed the capital currently available. This capital shortage is particularly difficult for companies outside the top-tier. I would be happy to discuss these matters further, if you desire. I can be reached at 415-496-1618.

Yours very truly,



Kenneth B. Lee, Jr.  
National Director  
Life Sciences Industry Services

### Effect of the "Breakaways"

(\$ Billions)

	<u>Total Industry</u>	<u>Excluding Biotech's Top Ten</u>
Sales	\$7.0	\$4.2
Revenue	\$10.0	\$6.8
Net income/(loss)	(\$3.6)	(\$4.1)
Market capitalization	\$45.0	\$28.0
Survival index	44 mos	28 mos

 ERNST & YOUNG

## Effect of the "Breakaways"

## 1993 Biotechnology Stock Report

Company	Symbol	12/31/92	3/31/93	6/30/93	9/30/93	12/31/93	YTD % CHG
Abaxis Inc	ABAX	6.00	5.25	5.25	7.25	7.00	17%
Adv Magnetics	AVM	12.35	12.50	13.25	13.00	12.37	-4%
Adv Poly Sys	APOS	8.35	6.75	6.75	6.00	5.25	-37%
Adv Tissue Sci	ATIS	14.00	8.88	8.50	8.63	8.25	-41%
Affinity Bio	AFBI	4.00	4.38	3.75	3.75	3.81	-5%
Affymax	AFMXF	20.25	16.00	14.75	15.00	14.75	-27%
Agouron	ACPH	13.00	9.25	10.00	9.25	11.75	-10%
AgriDyne	AGRI	5.00	4.00	5.25	4.63	4.75	-5%
Alamar Bio	ALMR	8.50	6.25	3.00	2.38	2.75	-58%
Alkermes	ALKS	8.50	8.00	7.25	7.75	7.00	-18%
Alliance	ALLP	11.50	9.75	8.88	10.25	8.00	-30%
Alpha 1 Bio	ALBH	15.50	11.25	11.50	17.25	14.50	-6%
Alpha Beta	ABTI	15.75	18.75	25.00	27.00	32.25	105%
Alteon	ALTN	15.50	11.00	10.00	8.75	8.50	-45%
Am Bio Sci	MABXA	5.50	5.13	3.63	5.38	4.88	-11%
Amgen	AMGN	70.62	37.75	36.50	38.63	49.50	-30%
Amylin	AMLN	11.25	8.50	9.00	12.00	13.00	16%
Anargan	ANRG	10.25	7.50	6.50	6.50	5.00	-51%
Aphtron	APHT	17.75	12.00	19.75	15.25	22.00	24%
Applied Bio	APBI	9.38	7.50	5.50	5.38	5.13	-45%
Applied Immune Sci	AISX	17.13	18.00	20.00	14.00	10.00	-42%
Appl Micro	AMBI	3.63	-	4.44	5.63	3.75	-58%
Apogenex	APG	8.75	-	-	5.50	5.50	-37%
Argus Pharm	ARGS	8.75	6.00	-	-	6.13	-12%
Arris Pharm	ARRS	7.00	-	8.50	7.50	8.25	6%
Athena Neuro	ATHN	7.75	7.25	7.75	6.63	5.88	-36%
Atrix Labs	ATRX	9.13	7.75	8.00	9.00	7.50	-42%
Autoimmune	AIMM	13.00	7.38	2.25	3.00	2.50	-60%
Balmac	BLM	6.25	3.13	9.63	9.75	10.38	-32%
Biochem Pharma	BCHXP	15.25	12.88	5.50	5.75	4.25	-37%
Biocircuits	BIOC	6.75	5.13	32.38	36.88	39.88	-15%
Biogen	BLEN	47.00	29.50	5.88	4.88	4.63	37%
Bioject	BJCTF	3.38	4.25	1.75	5.25	8.25	-15%
Biomatrix	BIOX	9.75	7.00	4.25	1.00	1.06	-15%
Biomerica	BMRA	1.25	1.18	7.25	10.63	7.13	-19%
Biomira	BIOMF	8.75	7.13	4.63	4.25	3.75	-69%
BioSurface	BSRF	12.00	5.00	7.50	6.75	5.75	-58%
Biosys	BIOS	9.25	9.00	2.25	2.00	1.03	-48%
BioTechnica	BTCC	2.00	1.63	6.13	5.63	5.25	-11%
Bio Gen Corp	BTGN	5.88	4.75	9.75	9.75	7.88	-19%
Biotime	BTIOY	9.75	9.25	10.88	11.00	10.75	-17%
British Biotech	BBIOY	13.00	13.75	14.13	13.88	13.13	-36%
Calgene	CGNE	20.62	10.75	4.75	3.38	2.50	-65%
Cambridge Bio	CBCX	7.13	5.75	8.00	9.38	7.75	0%
Cambridge Neuro	CNSI	7.75	8.50	8.75	7.25	6.50	-37%
Cantab Pharm	CNTBP	10.25	9.00	11.88	11.50	14.25	14%
Carrington	CRN	12.50	9.50	10.38	9.50	7.00	-47%
Calgene	CELC	13.13	11.38	13.50	18.00	19.50	77%
Cell Canesys	CECE	11.00	11.25	0.72	0.78	0.94	-62%
Cellcor	CLTX	2.50	1.03	21.25	23.75	34.75	65%
CellPro	CPRP	21.00	15.75	1.40	1.38	1.44	-25%
Cal-Sci	CELI	1.91	1.56	0.31	0.28	0.16	23%
Cellular Pred	CELP	0.13	0.31	7.75	7.38	11.00	10%
Caltex	CTCX	10.00	6.88	8.25	10.63	11.88	-27%
Cantecor	CNTO	16.25	6.75	12.25	15.00	16.37	46%
Cephalon	CEPH	11.25	10.25	0.87	0.75	0.88	-77%
Chantal	CHTL	3.88	1.31	-	-	-	-

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Company	Symbol	12/31/92	3/31/93	6/30/93	9/30/93	12/31/93	YTD % CHG
Chemax	CHMX	2.63	2.75	2.06	1.36	1.25	-52%
ChemTrak	CMTR	10.00	13.00	8.75	4.13	4.50	-55%
Chiron	CHIR	56.50	48.25	64.25	74.88	84.00	49%
Cholastech	CTEC	14.33	6.88	8.50	7.83	6.25	-57%
CoCensys	COCN	5.00	5.38	7.25	7.25	4.00	-56%
Coll Research	CRIC	1.50	2.13	1.25	1.63	3.75	150%
Collagen	CGEN	22.25	22.75	22.75	27.50	27.75	25%
Columbia Labs	COR	5.63	5.00	4.75	5.38	6.00	7%
Cor Therapeutics	CORR	15.00	10.75	13.25	13.75	15.13	1%
Cortech	CRTQ	10.75	9.00	10.25	15.75	13.75	28%
Cortecs Intl	CLVRY	3.56	5.13	3.00	4.13	3.75	3%
Cortex	CORX	1.56	1.63	1.44	2.25	1.81	16%
Corvas	CVAX	7.83	5.00	5.50	4.13	4.50	-43%
Creative Bio	CBMI	8.50	6.13	8.13	9.13	10.38	22%
Crop Genetics	CROP	5.38	4.63	3.88	3.00	2.06	-62%
Curative Tech	CURE	7.13	5.00	5.63	6.63	6.37	-11%
Cyanotech	CYAN	1.06	1.50	1.37	1.13	1.37	29%
Cygnus	CYGN	12.00	7.50	6.75	6.13	11.25	-6%
Cytei	CYTL	9.38	7.13	5.63	4.63	4.75	-49%
Cytogen Corp	CYTO	22.00	12.00	12.13	7.25	6.00	-73%
CytoTherapeutics	CTHI	7.75	5.88	7.50	10.75	12.25	58%
CytRx	CYTR	5.25	4.41	4.63	5.00	6.25	19%
DDI Pharm	DDIX	2.88	3.88	3.88	4.00	3.37	17%
DeKalb	SEEDS	28.00	32.00	27.50	25.75	31.50	13%
Deprenyl Animal	DAHI	2.50	2.00	1.50	2.63	2.13	-15%
Deprenyl Research	DEPR	5.50	3.06	2.94	2.19	1.81	-67%
Diagnostic Prod	DP	29.88	26.37	21.13	19.25	18.63	-38%
Dianon Systems	DIAN	11.00	8.00	8.37	7.00	6.00	-45%
DNA Plant Tech	DNAP	5.50	5.00	5.38	5.63	4.50	-18%
DNX Corp	DNXX	6.75	4.50	4.50	5.00	4.06	-40%
Dura Pharm	DURA	7.25	5.00	3.50	5.75	7.25	0%
Dynagen	DYGN	4.88	5.75	4.88	3.88	3.13	-36%
EcoGen	EEGN	7.88	5.88	7.75	6.75	6.25	-21%
EcoScience	ECSC	6.25	7.75	10.25	10.13	6.00	-4%
Embrex	EMBX	7.75	8.38	8.00	7.00	6.00	-23%
Emisphere	EMIS	17.25	11.38	14.50	9.63	9.00	-48%
Envirogen	ENVG	7.50	5.75	3.00	3.63	3.50	-53%
Enzo Biochem	ENZ	7.38	7.50	8.50	14.50	15.88	115%
Enzon Inc	ENZN	7.13	5.75	4.88	5.13	5.38	-25%
Enzymatics	ENZY	3.75	3.00	1.75	1.00	0.53	-86%
Epigen	EPNEC	1.67	1.41	1.09	2.38	2.00	20%
Epitope	EPT	18.00	17.75	19.88	21.50	20.37	13%
Escagenetics	ESN	9.00	7.50	6.13	8.00	4.63	-49%
Fountain Pharm	FPPI	1.13	0.81	0.84	0.78	0.59	-48%
Future Med	FWPI	1.31	1.47	1.25	1.22	0.81	-38%
Geneiabs	GNLB	6.75	6.38	5.88	4.25	4.19	-38%
Genentech	GNE	37.38	36.13	44.00	42.88	50.50	35%
Genetic Therapy	GTII	10.50	12.13	17.25	18.25	16.25	55%
Genetics Inst	GENZ	32.25	28.38	31.00	41.25	48.25	50%
Genisa Pharm	GNSA	24.50	16.00	23.25	26.50	24.75	1%
Genta Inc	GNTA	9.00	7.50	8.00	9.00	7.38	-18%
Genzyme	GENZ	45.25	34.50	39.00	33.50	27.50	-39%
Genzyme Trans	GZTC	8.00	-	-	7.00	6.75	-16%
Glaxo Sciences	GLD	19.25	12.25	16.38	14.50	12.00	-38%
Glycomed	GLYC	11.00	7.75	7.00	8.30	7.25	-34%
Greenwich	GRPI	6.75	5.63	5.00	2.43	2.75	-59%
Memcare	MEMA	8.50	6.88	5.63	6.25	5.75	-12%
Houston Bio	HBIO	5.00	-	-	-	2.63	-47%
Human Genome	HGSI	12.00	-	-	-	17.75	48%
Mycor Bio	MYBD	5.75	5.63	4.31	4.13	4.50	-22%
Idex Corp	IDCS	7.63	6.13	6.00	5.50	5.63	-26%
IDEC Pharm	IDPH	8.75	5.75	5.50	5.00	5.75	-34%
Idexx Labs	IDXX	32.75	35.25	36.50	49.00	31.88	-3%
ICI Labs	ICLI	10.50	11.00	9.00	8.25	8.25	-21%
ICI Inc	IC	10.25	10.37	10.63	8.75	8.88	-13%

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Company	Symbol	12/31/92	3/31/93	6/30/93	9/30/93	12/31/93	YTD % CHG
ImClone Sys	IMCL	11.50	9.25	6.00	9.25	6.13	-47%
Immucell	ICCC	1.31	1.31	1.31	1.44	1.91	46%
Immucor	BLUD	7.13	7.25	6.00	6.13	5.81	-13%
ImmunoLogic	IMUL	11.25	9.50	10.00	9.75	13.50	20%
Imm. Resp	IMNR	19.25	11.75	12.75	10.50	10.25	-47%
ImmuneX	IMNX	30.25	24.50	31.25	18.50	16.25	N/A
ImmunoGen	IMGN	10.50	6.50	6.50	7.50	9.13	-13%
Immunomed	IMMU	11.13	7.63	7.00	6.63	5.50	-51%
Imra	IMRE	3.00	2.62	2.75	3.63	3.88	29%
Imutac	IMUT	3.81	2.75	2.38	1.88	2.13	-44%
Incyte Pharm	IPI	7.50	-	-	-	9.00	20%
InnoVet	IVT	1.68	1.88	1.31	1.13	0.92	-45%
Innovir	INVR	5.25	-	-	4.38	12.00	129%
InSite Vision	INSV	11.00	-	-	-	10.50	-5%
Interferon Sci	IFSC	3.25	2.13	4.00	4.50	4.69	44%
Inti Murax	MOX	7.63	5.00	4.75	6.63	5.13	-33%
Internaureon	IPIC	10.88	7.00	8.75	8.13	10.13	-7%
Isis Pharm	ISIP	9.75	6.13	6.38	6.25	6.75	-31%
Ivax Corp	IVA	29.25	24.13	25.25	25.88	28.75	-2%
Lidax Pharm	LDAX	0.88	2.50	3.34	8.63	7.06	702%
Life Tech	LTEK	21.75	20.25	17.63	19.75	18.50	-15%
LifeCell	LIFC	11.50	8.25	10.00	11.50	9.13	-21%
Lifecore Bio	LCBM	8.13	6.00	7.50	7.63	9.88	22%
Ligand	LCND	10.50	9.75	9.50	10.25	11.75	12%
Liposome Co	LPO	11.75	8.00	7.38	6.38	6.63	-44%
Liposome Tech	LTIZ	10.00	7.25	9.25	10.25	9.00	-10%
MacroChem	MCHE	6.31	3.50	4.75	6.00	3.37	-47%
Maganin	MAGN	8.25	5.75	7.75	11.50	13.75	67%
Martek Bio	MATK	7.00	-	-	-	9.00	29%
Mattech	NMPS	5.00	2.50	2.00	1.38	3.38	-32%
Matrx	MATX	8.75	6.75	9.00	9.50	10.50	20%
Medarex	MEDX	8.00	6.50	5.50	6.13	7.75	-2%
Med-Chem	MCH	11.00	11.25	8.00	7.25	6.88	-37%
Medicis	MDRX	1.69	1.06	0.75	0.59	0.50	-70%
MedImmune	MEDI	23.00	14.50	19.13	22.00	11.00	-52%
Meridian Diag	KITS	9.00	9.95	9.47	8.50	8.75	-3%
MGI Pharma	MCGN	12.25	8.25	14.00	14.00	14.75	20%
MicroGene	CARB	5.50	5.00	6.00	6.00	7.00	27%
Microprobe	MPRO	6.50	-	-	5.63	4.50	-31%
Molecular Bio	MB	20.88	18.25	22.00	25.75	18.63	-11%
MycoGen	MYCO	14.00	12.25	13.25	12.75	10.25	-27%
Neogen	NEOG	2.94	3.00	3.00	4.87	5.38	83%
Neoprobe	NEOP	8.00	5.50	6.37	6.75	6.25	4%
NeorX Corp.	NERX	3.75	2.41	2.38	2.31	2.38	N/A
Neurex	NXCO	5.00	-	-	5.25	4.00	-20%
Neurogen	NRGN	8.25	5.75	6.75	6.13	6.63	-20%
North Am Bio	NABO	2.81	2.31	3.19	3.38	3.31	18%
North Am Vaccine	NVX	10.13	9.25	9.88	9.50	11.00	9%
Noven	NOVN	12.88	10.50	11.25	11.88	14.13	10%
Oncogene Sci	ONCS	6.00	5.75	4.50	4.00	3.75	-38%
Oncor Inc	ONCR	7.00	5.63	5.75	7.75	10.37	48%
Organogenesis	ORC	9.00	9.00	3.63	7.00	9.00	0%
Osteotech	OSTE	7.00	7.50	6.00	6.13	4.88	-30%
Panadarm Inc	DERM	11.00	-	-	-	11.37	3%
ParSeptive Bio	PBIO	21.75	17.38	19.50	22.00	28.75	32%
ProCytex	PRCY	9.63	9.13	11.50	12.50	14.00	45%
Protein Design	PDL	11.38	7.63	12.25	14.13	24.25	104%
Protein Polymer	PPTI	1.88	1.38	0.38	0.75	0.56	-70%
Quadra Logic	QLTF	7.75	10.00	8.50	8.50	7.88	2%
Quidel Corp	QDEL	4.38	4.25	4.50	4.25	4.63	6%
Regeneron	REGN	12.00	15.25	16.50	15.50	15.50	23%
Reoligen	RCEN	9.50	7.00	7.00	6.75	6.88	-28%
Ribi Immuno	RIBI	9.38	6.13	5.50	6.00	9.38	0%
SangStat Medical	SANG	7.00	-	-	-	7.00	0%

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Company	Symbol	12/31/92	3/31/93	6/30/93	9/30/93	12/31/93	YTD % CHG
SciClone	SCLN	17.25	16.50	15.38	18.50	23.00	33%
SciGenics	SCGN	6.75	4.25	5.00	6.75	9.38	39%
SciGen Nova	SCNO	9.25	7.00	5.63	7.50	10.25	11%
Sepracor	SEPR	9.50	9.25	8.88	8.75	6.50	-32%
Seragen	SRGN	12.25	9.13	8.50	8.75	6.50	-47%
Shaman*	SHMN	15.00	10.75	13.00	13.50	11.75	-22%
Somanetics	SMTS	4.75	3.88	3.56	4.13	1.75	-63%
Somatix	SOMA	5.50	5.75	7.13	7.50	8.50	-11%
Somatogan	SMTC	19.75	12.50	9.50	11.50	9.50	-52%
Sphinx	SPHX	7.00	4.75	3.13	2.88	2.88	-59%
Synbiotics	SBIO	3.25	4.00	3.13	5.13	4.00	23%
Synbiotics	SYCN	64.25	10.63	11.63	10.75	11.38	-82%
SynGene	SYNG	4.88	4.63	3.75	3.25	2.75	-44%
Syntro	SYNT	23.13	20.00	18.50	17.63	17.75	-23%
Systemix	STMX	7.38	6.13	6.50	6.38	7.75	5%
T Cell Sciences	TCEL	27.25	19.50	22.25	23.00	17.38	-36%
Telios Pharm	TLIO	7.38	5.75	6.50	5.50	5.25	-29%
Telior Ophth*	TELR	8.00	-	9.00	5.25	4.25	-47%
Teva Pharm	TEVY	26.33	27.16	20.63	29.63	30.13	14%
Theratech	THRT	15.25	15.50	12.75	14.25	15.00	-2%
TSI Corp	TSIN	5.75	2.06	1.25	1.25	0.94	-84%
Unigene	UGNE	4.19	3.31	3.13	2.75	2.50	-40%
Univax Bio	UNVX	10.75	7.50	8.50	7.88	7.25	-33%
US Bioscience	UBS	11.13	7.50	7.63	9.63	8.37	-25%
Vertex Pharm	VRTX	9.75	8.00	9.50	12.75	18.50	90%
Vestar Inc	VSTR	15.75	11.25	8.00	9.00	6.25	-60%
Viagen Inc*	VIGN	9.00	-	-	-	9.63	7%
Vical Inc*	VICL	5.00	6.25	9.25	8.50	13.50	170%
VimRx	VMRX	1.88	1.31	1.31	1.88	1.44	-24%
Viratek	VIRA	6.58	11.63	12.50	13.88	10.75	58%
XOMA	XOMA	9.63	7.50	8.88	5.63	5.25	-45%
Xytronyx	XYX	7.00	5.13	7.88	10.13	8.25	18%
Zonagen Inc*	ZONA	5.50	-	5.00	5.63	9.25	68%
Zynax Inc	ZNAX	6.12	5.38	5.25	5.13	4.63	-25%

\* Initial public offerings in 1993. First price listed is IPO price. % change calculated from IPO price.

\*\* Trade in ADRs.

\*\*\* As a result of Immunex Corp.'s merger with American Cyanamid subsidiary Lederle Oncology Corp., Immunex shareholders of record on June 1 received \$21 in cash for each share of stock owned and one share of new Immunex stock. First two quarters were adjusted to reflect this change.

\*\*\*\* 4-for-1 reverse stock split in fourth quarter.

# Private Placements by Public Companies Life Sciences Industry 1993

Company	Amount (\$ millions)	Month	Price (\$)	Quantity (un)	Yield (%)	Use of Proceeds	Product Status
Almar Biociences Inc.	\$2.00	September	\$2.00	1,700,000	30-30%	Commonwealth Associates	Products on market
Alpha Beta Technology, Inc.	\$20.0	July	\$20.00	1,000,000	10%	Vedco Securities International	Various clinical phases
Canguard Pharmaceuticals	\$1.3	July	\$0.25	5,200,000	n/a	Treatment for Parkinson's	Prediction products
Canab Pharm	\$5.0		\$1.52	3,300,000	n/a	Leukocyte modulation and therapeutic antigens for transplant rejection, cervical cancer, and other diseases	Various clinical phases
Cellite Pharm	\$10.5	June	\$5.94	1,700,000	10%	Compound title	Various research and clinical phases
Capitol Inc.	\$3.0	August	\$10.50	285,000	0%	Diagnostic and therapeutic agents for diseases of the nervous system	Various clinical phases and development
Creative Biomolecules Inc.	\$18.0	August	\$5.50	2,600,000	12%	Therapeutic for human tissue repair and regeneration	Various clinical phases; products on market
Cyanotech	\$0.6	August	\$1.00	550,000	n/a	High-value products from microalgae	Products on market
CytioTherapeutics	\$18.8	October	\$7.50	2,500,000	12%	Implantable drug delivery for central nervous system diseases	Various clinical phases; filed IND
Dura Delivery Systems	\$13.0	September	\$10.00	1,300,000		Drug delivery systems for asthma and chronic obstructive pulmonary diseases	
Dynagen Inc.	\$4.5	June	\$4.00	1,100,000	7%	Diagnostics tests for Tuberculosis	
Enogen Tech. I	\$30.0		\$100,000	300 un		Bioprocesses for use in agriculture	Development phase; products on market



# Private Placements by Public Companies Life Sciences Industry 1993

		(millions)							
Company	Offering Date	Offering Price	Amount	Offering Type	Underwriter	Product	Phase	Product	Phase
Ento Biochem Inc.	7/2	\$7.2	\$9.00	900,000 sh	30%	Anticancer drugs to treat viral diseases and cancer			
	8/1	\$5.1	\$8.50	546,297 sh					
ESCAgenetics	8/1	\$8.1	\$4.50	1,800,000 sh	30-35%	Plant derived pharmaceuticals and food	Various research phases; products on market		
Gensia Pharm Inc.	8/20	\$8.0	\$50.00	1,600,000 convertible preferred shares		Therapeutics for the treatment of human diseases; drug for treatment and diagnosis of cardiovascular disease	Various clinical phases; New NDA		
Genta	10/20	\$24.0	\$50.00	477,540 un	n/a	Anticancer therapeutics, dermatology products, and oral drug delivery	Various research and clinical phases; products on market		
Greenwich Pharmaceuticals	11/8	\$11.8	\$3.88	3,000,000 sh	30-35%	Synthetic carbonylhydrazide for chronic autoimmune diseases	Various clinical phases		
	8/0	\$8.0							
HemaCare Corp.	2/0	\$2.0	\$5.00	400,000 sh	25%	Passive hyperimmune therapy for AIDS	Phase II clinical; products on market		
Hydral Holdings, Inc.	3/13	\$31.3	\$1.05	1,250,000 un	n/a	Monoclonal antibodies for cancer			
International Murex Technologies Corp.	2/6	\$2.6	\$5.25	500,000 un	n/a	Diagnostics for infectious diseases and blood transfusions	Products on market		
	3/7	\$3.7	\$5.25	710,800 un	n/a				
ImmuCell	3/3	\$3.3	\$1.75	180,000 sh		Infectious disease prevention and treatment products for animals and humans	Various clinical phases; products on market		
Inne Corp.	5/0	\$5.0	\$2.25	889,000 sh	0%	Human therapeutics			
Innovet Inc.	5/0	\$5.0	\$1.38	4,000,000 sh	15%	Drug delivery technologies in veterinary and human medicine	Predictions and registration		

# Private Placements by Public Companies Life Sciences Industry 1993

Company	Offered (\$ millions)	Date	Price (\$)	Size (un)	Yield (%)	Use of Proceeds	Status
Interferon Sciences	\$10.0	June	\$4.00	2,500,000 un	n/a	D. Blech & Co.	Natural-source, multisubspecies leukocyte IFN; Clinical applications in viral diseases, AIDS products on market and cancers; Lymphokines
MacroChem Corp.	\$7.5		\$52,500	142 un	n/a		Various preclinical and clinical phases
Magainin Pharma.	\$19.3	October	\$8.75	2,200,000 sh	7.50%	Hambrecht & Quist, S.G. Warbur	Various clinical phases
Medical Polymers Technologies, Inc.	\$2.5	September	\$250,000	10 un	n/a	None	Polymer drug delivery system
MedImmune Inc.	\$21.0		\$18.50	1,120,000 sh	10%	Vector Securities International	Therapeutics and vaccine for infectious disease-Various research and clinical phases; Bld F products on market
NeoRx Corp.	\$9.0	July	\$2.00	4,500,000 sh	11%	Dakra Securities America Inc.	Monoclonal antibodies for cancer
Nation Pharm Inc.	\$9.0					D. Blech & Co.	Calinase therapies and protein drug delivery systems
Pharmos Corp.	\$10.0		\$1.50	6,700,000 sh	23%	Tucker Anthony and D. Blech & Co.	Drug delivery for diseases of the eye and central nervous system
Quada Logio	\$16.5	July	\$9.25	2,000,000 sh	6%	Nesbitt Thomson, Scotia McLeod	Photodynamic therapy
Xytronyr Inc.	\$1.7	July	\$5.00	300,000 sh	n/a	and Gospel Shields & Partners	Various clinical phases; products on market
							Vaccines, protein chemistry and synthetics, enzymology

Mr. RAAB. I really speak not for Genentech in this case but for the biotechnology industry association that I chair, and I am also on the board of a number of very small both private and public companies, and I've seen the tremendous pressure that they have had in raising money. They have raised some money, but it has been much more expensive as far as the dilution is compared and they have raised less money this year.

Genentech, we have raised in the capital markets almost \$1 billion. Not many people have done that, and it is a lot of work and it is not easy to do. But I'm glad we did it when we did it and I'm glad I don't have to do it now. Because the fact companies are raising \$18 million or \$22 million or so, that is peanuts for what it is going to take to get their first product to market, to build the factory and do all the research.

I think the damage done to the industry in the past 12 months as far as the capital markets only bodes for something worse to come if the legislation is not done appropriately.

Mr. MCMILLAN. It's so easy to focus on the profitability of pharmaceutical companies or technology companies and say, well, they're just walking away with this and ripping off the American public, when in fact we know that most vibrant businesses are probably plowing back everything they earn. Their cash flow from depreciation or amortization of prior investments probably go into capital markets and investing far more than the profits would indicate, and most of it is being plowed back into the development of new product.

I think educational information on that line would be useful. I guess people are going to demagogue the issue if they are going to demagogue it anyway, but I think it is important that it be understood.

Let me shift just for a minute and focus on one thing that is used to highlight the problem. The differences in pharmaceutical prices between the United States and the United Kingdom has been one used. But basically the major pharmaceutical markets in the world in addition to the United States are, would it be correct to say, Japan, Canada, United Kingdom, France, Germany, and Italy? All of them have controlled price structures on pharmaceuticals?

Mr. VAGELOS. Yes.

Mr. MCMILLAN. Is it fair to say that because we don't, then maybe the American consumer ends up paying a disproportionate share for research and development costs that may be built into those products?

Mr. VAGELOS. Let's take two parts of the question, Mr. McMillan. The first is, why are there differential prices? As was mentioned earlier by one of our speakers, when a drug is introduced throughout the world by any of us, most of us try to introduce it at the same price everywhere. And we do, where we can. Where we do not, we are prevented by price controls. So artificially some prices are restrained.

There is a difference in the prices as you go out in time, as was demonstrated by one of the charts that we saw earlier, by the effect of currency exchange rates. The dollar either strengthens or weakens, and when it strengthens, you get much less back from your foreign sales revenues and income than you would otherwise, and

there is a tremendous differential as you got out in time as the dollar continues to strengthen with relation to other products. So you have that effect.

You have another effect, and that is in some countries there are patents and some there are not. In those places that don't have good patent protection one has immediate generic competition, so you have enormous differentials there. You do have the use of generic drugs in the United States very much more vigorously than other countries, and therefore, if one goes out and looks at comparative prices, one could look at the brand name price in the United States and not look at the generic price in the United States and compare only the brand name. So one gets a false impression.

The answer is, sure, there are differences and they are hard to control, but we would love to have them stay at the place where we start them.

Second, does the United States fund research because of our pricing structure? The answer has to be yes to some degree in that this is the largest market in the world. It is interesting that Dr. Sanders and I have two major companies, number one and two in the market, and both of us have almost the same percent of our sales in the United States.

This is the engine that drives pharmaceutical research throughout the world. Whether the discovery is in the United States, the United Kingdom or Switzerland or Germany or Japan, the market that drives that research is the United States. Therefore, the question you have to ask yourself and the people of the United States have to ask is, is it worth having the most vigorous, competitive, export-related or productive high tech industry in the world that works on health care and reduces health care costs by the products of what we do, is it worth having that in the United States versus some other country? I would say that in my opinion, as a physician and as a potential patient some day, I hope we keep it here.

Mr. WAXMAN. Mr. McMillan, your time has expired but Dr. Sanders wants to respond. If he would briefly, then we are going to move on.

Mr. SANDERS. I think that the American consumer benefits very substantially by having the availability of these breakthrough drugs, since we are talking about those, or indeed the wide variety of pharmaceuticals as a result of the marketplace in which we operate and the research that we do. So although other countries certainly benefit, the American patient benefits primarily first and foremost, and that's really what it's all about as far as I am concerned as a doctor and as a pharmaceutical company chairman.

Mr. WAXMAN. Thank you very much.

Mr. Towns.

Mr. TOWNS. Thank you very much, Mr. Chairman.

Why can't we rely more on the government research for new drug development? Are we overly dependent on private drug companies in the research arena?

Mr. VAGELOS. The way we are organized in research here, the government, principally represented by the National Institutes of Health and to some degree by the National Science Foundation, funds research at universities and intramurally at the National Institutes of Health. Their work is done through scientists and stu-



dents and postdoctoral fellows. The product of their work is pure basic research. They are not organized to do applied research.

Could they do it? Of course they could. They could if they wished, but it would be inappropriate in the setting, that is, in a university to do applied research, because that implies when you are doing applied research that you invest many, many years, million and millions of dollars to do one project, and that is inconsistent with what goes on in the universities.

It also implies that you have to keep some information rather quiet, and that is also inconsistent with what should happen in universities.

So I think our system, which is organized to have pure basic research, fundamental knowledge coming out of the government funded research and industry then picking it up and doing the applied research, is wonderfully productive. I don't think we would want to change it. I wouldn't want to change that.

Mr. TOWNS. Even if they put the additional money, \$200 million, that really would not solve our problems with it. If they increased it \$200 million and put it in there for research, that would not really solve our problem.

Mr. VAGELOS. No. The budget of the National Institutes of Health is something like \$9 billion. The research budget of the industry is \$11.5 billion. Therefore, to add \$200 million to the government sector gets you nothing. Merck alone spends \$1.2 billion a year. So it would take years for the government to gear up and to bring in the kinds of chemistry that needs to be done to do the kinds of work that ultimately results in products. Not a very effective system.

Mr. RAAB. Let me comment from the perspective of building a company. When I joined Genentech we were 10 percent of the size. That was less than 9 years ago. I've worked in the large pharmaceutical industry for most of my career, so I have a fairly broad perspective on it.

I start by saying we have yet to find—and we have looked at it to make sure when I say this, because I do say it with some frequency—there was never a drug discovered and developed in a communist country. There are some discoveries that were eventually translated in developments in our country or in Europe. The driving force of the free enterprise institution that private companies have—and you see it in small companies—on New Year's Eve there were 60 people working at Genentech on a project which I'm not going to tell anybody in this room about.

Mr. VAGELOS. We know about it already.

Mr. RAAB. Dr. Vagelos says we try to keep secrets. And we had lawyers there writing patents. I went over and took some liquid refreshments towards the end of the evening and had the spouses of the people come, because we wanted to get this project done in 1993. I use that symbolically. The kind of driving force—we see it in all industries—of the free enterprise system, that is not the way we've seen institutions, academic and governmental institutions. They play a tremendously important force in creating the basic science, but to take a drug to market, commercialize a product, it's a different type of activity, and I think it only happens—

Mr. VAGELOS. I have to interject. I was at NIH when the genetic code was done, and the excitement can be equally exciting in pure basic research, but the division of labor is terrific as it is organized today, and I don't think we ought to change it.

Mr. TOWNS. Thank you.

The Lewin analysis shows that the average drug company will lose almost 7 percent of its revenue. This morning Dr. Lee, I think, testified and indicated that the administration says you will get a windfall. Who is right?

Mr. MOSSINGHOFF. Congressman, we first had a study done for PMA by Dr. Don Muse, a recognized health economist, and he said that the losses to the brand name side of the industry would be somewhere between 6 and 11 percent. Lewin did their study totally independent of the PMA and I think any other industry, and they said the average brand name company would lose 6.7 percent.

We're very interested in seeing some of the results of the information. We have been trying to get the results of the government's information where they say there are going to be increased sales in the brand name side. We tried over the weekend to run a model to see whether or not we could duplicate those numbers. The only way we could do it was to say that induced utilization has to be somewhere around 33 or 35 percent. In other words, 33 or 35 percent more prescriptions dispensed. That is off, we think, by a factor of 3. Most of people who look at it—they did in catastrophic and they did otherwise—say there is between 8 and 10 percent increased use through induced utilization.

We're still trying to get the data from the government to see where they get those numbers, because both the Lewin study, which had nothing to do with PMA, and our own study indicate that those numbers are way off. Maybe the committee can help us do that.

Mr. TOWNS. Thank you very much. I yield back, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Towns.

Mr. Hastert.

Mr. HASTERT. Thank you, Mr. Chairman.

In the administration's testimony this morning they testified that there are no price controls on pharmaceuticals in the President's bill. I was also looking through the testimony of one of the economists that are going to testify later on today, Mr. Lott. Basically, he says that a study of 560 economists reported that they believe the Health Security Act contains price controls or virtual price controls. He disagrees with the administration on this issue. Fees charged by doctors and hospitals, premium caps and annual global budgets for health care amount to price controls.

Dr. Sanders.

Mr. SANDERS. Well, the global budgets and setting premiums and the rate of premium growth, by any other name, seems to me to be price controls. Certainly if you are going rebate 17 percent and have to go through a drug price review board and have the Secretary have the power to blacklist your drug based on what is perceived on the part of the Secretary's view to be excessive pricing, by any other name, I think that has a very strong element of price control. I don't know what you want to call it. What I would say

is that it's not a free market, and that is really what we would like to operate in and that is what we are asking for.

Mr. HASTERT. Mr. Raab, do you want to speak to that?

Mr. RAAB. I certainly agree with what Dr. Sanders said. I think the financial markets, which in the long run are very wise, have demonstrated that these are forms of price controls. They may be veiled, but that is going to be the net result.

When you have people saying the breakthrough drug committee is not dangerous, you think of a small western town where somebody is wondering why nobody starts a new business when there is a scaffold in the middle of town and the sheriff walks around with a big rope under his arm. I think this has some of those implications.

Mr. HASTERT. That takes care of neck pain.

Maybe this is a little bit presumptuous. If you had a crystal ball and you had two situations before you, could you describe on the par that you are on today, with basically the free market driving what your research is, with the products you are bringing on board, and how you run your business, where do you think your companies would be 2 years from now? And in contrast, if the President's bill would be enacted, what would be the changes in how you would operate your company?

Mr. VAGELOS. I can begin and say that if all the parts of the President's bill were passed, funding long-term research, which is so risky, would definitely be reduced. There is just no question about it. We could not afford to do that. So we would cut back. Both the number and the riskiness of the projects would be reduced simply because we couldn't take that much risk for that much money, and we would be a different kind of company ultimately.

Mr. RAAB. In our case, I think the growth would probably slow if not stop in research investment. Much more importantly, and I think more seriously, we would work on fewer projects with small numbers of patients and we would look at more projects where there was a larger patient base. The other fundamental aspect of it, we would work on projects where there is more fundamental biological and clinical knowledge.

Dr. Vagelos talks about what Merck has invested in AIDS. We've invested over \$125 million, unsuccessfully so far, although we have a product in clinical trials right now as a vaccine and as a potential therapeutic. The board sometimes challenges me why I'm putting so much money in an area that is incredibly high risk. Very complicated, obviously, from a societal point of view in the country and the world. I think that would affect what we would invest in some of those high risk things significantly.

Mr. SANDERS. I would only add that we already are dealing with a marketplace that is changing very rapidly and the fact is we are restructuring our companies to deal with these particular changes, and that is going to continue no matter what happens as far as health care reform is concerned.

To get to Dr. Vagelos' point, I think what we would do as a research strategy is wait for someone else to discover that breakthrough molecule. Then we would tweak the molecule, if you would, chemically to make a significant and incremental benefit to



its action, but we wouldn't take that high risk. Somebody else could take that high risk, probably in a foreign country.

What we would do, by the way, is we would export the breakthrough opportunities overseas and really contribute to the ability of a foreign power or foreign company to steal the march on us in terms of breakthrough research.

Mr. HASTERT. Thank you.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you.

Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman.

We heard from an earlier panel this morning that about 16 percent of the manufacturers' price of a drug goes toward research and development, compared to about 36 percent towards marketing, advertising, profits. Those witnesses argued that the President's proposal requiring up to a 17 percent rebate on drugs sold to the Medicare program is not unreasonable.

Any of you may answer, but in light of your statements, Dr. Vagelos, about the rate of change, the rate of research being arrested, I wonder if you would comment on that.

Mr. VAGELOS. Yes. Let me just mention the 17 percent rebate. I think any kind of an imposed rebate on a program such as Medicare, which is what was discussed, is going to be damning to the system, because government imposed rebates are just very tough to deal with. I would suggest that there be considered a different kind of program for Medicare that would open it up to some competition, and that is, managed competition of pharmaceutical benefits for Medicare. What I am suggesting is the possibility of having pharmacy benefits management companies come in and bid for the business that will come from the Medicare prescription drug benefits.

The reason I say that is that managed care is happening in the United States. For instance, in the United States, about 50 percent of Merck revenues come from managed care groups.

There is an analogy on the pharmacy side, and that is pharmacy benefits management, which is a type of business which says the following things. Drugs can be managed; just as hospitals and doctors can be managed, prescription drugs can be managed. And they can be managed to do some of the things that were requested around the table this morning. That is, drug utilization reviews are done so people can be sure that two prescriptions of the same drug are not given to the same elderly person in different cities, that drugs that interact are not given. There are many services that can be done by a pharmacy benefits management group that improve the outcome of the patient using a drug.

In addition to that, by requesting discounts from pharmaceutical producers, pharmacy benefits management groups can produce programs for buyers, in this case Medicare, and it could be done along lines of regions within HCFA, to compete for the pharmaceutical business of these units and deliver a program that would give better drugs, better utilization of the drugs, better care of the patients for the lowest cost, and I would suggest that the cost would be better than the 17 percent rebate.

Mr. BROWN. Most of you negotiate prices for your product with large purchasers, institutions, managed care plans, and the like.



Mr. VAGELOS. And that is increasing.

Mr. BROWN. You say that's a good thing. Medicare as a large purchaser of prescription drugs under the President's plan, why shouldn't they also be able to negotiate prices with you?

Mr. VAGELOS. I didn't say it's a good thing. I said it's happening.

Mr. BROWN. You are accepting that it's happening.

Mr. VAGELOS. It's happening economically. It is the free market that is happening. I say, why can't that be extended into Medicare so that you have the free market-based managed competition. The pricing in 1993 was quoted by several people this morning as 3.1 percent. What that does not include is the deep discounts that are being done in the marketplace. When one sells to a large managed care group, whether it's an HMO, PPO or PBM, whatever these acronyms are, one always has to discount, and the discounts can be 10, 20 or 30 percent, and you don't see that in the published prices. So the 3.1 percent does not include that.

Mr. BROWN. I would bet that all of you gentlemen sitting at this table think that we have got to deal with government spending better than this Congress has done; we've got to do deficit reduction; we've got to move more aggressively than perhaps we have. But you don't think that Medicare should be one of those large purchasers than can save the government money by doing that same negotiation that seems to work with the private sector, with these business groups that you are talking about?

Mr. MOSSINGHOFF. Congressman, if I can respond to that. I think the feeling is that the government is too large a purchaser in that case. Medicare is one third of the market. If these gentlemen deal every day with smaller managed care, maybe one will win the contract one time and another will win the contract the next time, and you still have a lot of incentives for research and development. If you have someone in Washington deciding that for this year or for the next 2 years this drug is the preeminent drug or the only drug to be reimbursed under Medicare, that takes all the incentive out of all the other companies to want to compete in that drug area.

It's a classic marketplace situation where you have a lot of tough negotiations, and one time Dr. Vagelos will win and one time Dr. Sanders will win. If it's a third of the market, which is what Medicare is, it's too big a market to give that power.

Mr. RAAB. Generic drugs as we know them today in the United States and this whole dynamics of the generic force, which is the most beautiful symbol of free market happening, that doesn't happen when you have a single buyer. It just doesn't. Why would you do it? You'll see much, much less competition than we have happening in this country, and it's going to grow in the future.

I would point out that in the administration's proposal, I understand they are assuming 25 percent generic drugs. It is already beyond that. I think the opportunity of the dynamics of this reducing health care costs are incredible, and it is being missed in the proposed legislation.

Mr. BROWN. If you break this huge government up into a novel idea, a group of health alliances that are then smaller, they then could go out and make these purchases.

Mr. VAGELOS. Yes. I think they would engender enormous competition among the groups that would compete for the business of each of those accountable health plans or alliances.

Mr. BROWN. Thank you, Mr. Chairman.

Mr. VAGELOS. It would be very interesting, I might add, should you want, to look at all the controlled markets and see what percent of market share is held by generic drugs. You will find remarkable differences between Japan, Germany, Italy, the United Kingdom. Remarkable differences being driven in the United States because there is a free market.

Mr. ENGMAN. May I comment, Mr. Chairman, just briefly?

Mr. WAXMAN. Yes, Mr. Engman.

Mr. ENGMAN. I certainly agree that we need to have competition for this market, and it is true that the generic industry, as I have indicated in my statement, has provided significant competition and has helped to keep drug costs lower than they otherwise would be in terms of Medicare and other programs.

I think it's also interesting, however, to note that even though we are doing a better job of that in one sense, as Dr. Vagelos said, than perhaps in some of the controlled situations in Europe, here we can do a better job. My information is that in 1992 close to \$20 billion of brand name products were sold at the retail level for which there was a generic substitute. To the extent that we can continue to work to improve competition from generic products, I think we can go a long ways toward solving some of these additional cost problems that will come about because of providing a drug benefit.

Mr. WAXMAN. Mr. Brown, if you would permit.

Dr. Vagelos, are you suggesting that either the alliances or something at a local level act as a pharmacy management group for Medicare to negotiate the prices and to push the system for the best utilization?

Mr. VAGELOS. No. I'm suggesting that pharmacy benefits management groups compete for the business of either the accountable health plans in a region or the alliance.

Mr. WAXMAN. Including Medicare?

Mr. VAGELOS. Yes. Specifically Medicare.

Mr. WAXMAN. I think that's an intriguing idea. I want to follow up on that.

Mr. Upton.

Mr. UPTON. Thank you, Mr. Chairman.

I know that there are a lot of us on this subcommittee that are very concerned about price controls as evidenced by the questions that we have heard so far today. Particularly startling, of course, is the fact that in the last 2 years the pharmaceutical industry in fact has cut back, RIFed, fired, laid off, I believe, 38,000 employees in the pharmaceutical industry, and that is without price controls. The fear is that if price controls come about that in fact you will see our pharmaceutical industry in this country, which has been a real giant, really move off shore as they begin to do things and the American public would suffer in a host of areas.

As I have looked at some of the other schemes that other countries have had on pricing, I know that in France and in other places they have in fact imposed some price controls. I would like

to hear from each of you in terms of your thoughts on that, particularly in relation to my understanding that the European Commission is anticipated to soon issue new guidelines recommending that the United Kingdom and other European countries reform their systems to look more like America's because they recognize the pitfalls of the heavily government controlled and regulated systems.

I would appreciate each of your comments on that supposed study that is suppose to come out soon.

Mr. SANDERS. Let me start off. I think that in our experience in Europe we find that in the cost controlled or price controlled markets that the percentage of the health care dollar, if you will, allocated to the pharmaceuticals in those markets is much higher than we have here in the United States, some 15 plus or minus percent. Those are systems which clearly and overtly advocate low cost alternatives instead of breakthrough drugs and the adoption of new technologies.

So I just wonder what the wisdom is of that particular approach in serving the needs of the patients. I would argue that as a physician myself that you really want to have a wide array of new technologies and pharmaceuticals available to you because, in the final analysis, that improves the quality of life and is the most cost-effective. I think they are being penny-wise and pound-foolish.

Mr. UPTON. Would anyone else like to comment?

Mr. RAAB. I really don't have a lot to add, but I do think it's an opportunity to bring out a situation that has happened with Kaiser Permanente that I think is a wonderful example of the way it should happen. We have a heart attack drug called Activase TPA. In the early years when it was introduced we did not have substantive clinical evidence that it saved more lives than a much less expensive product. About 10, 12 percent of their utilization of these class of drugs was in our product and the rest was the much cheaper drug.

We spent \$50 million to do a study, which fortunately demonstrated that our drug did save more lives and provided other significant clinical benefits, and Kaiser Permanente is, I understand, in the 60 plus percent range and growing in its utilization because it realizes it brings the value to the patients.

I think it is so important as we think about all of these things that we think of patient value and not just unit cost, which is one of many, many aspects of the final value decisions for providing quality care to our patients in this country.

Mr. VAGELOS. I think the European community is reviewing what is happening, for several reasons. One is they believe that their health care costs are going through the ceiling and they can't control them and they have not had an active marketplace dealing with their costs in any sense. They are looking at the U.S. system. So as we are looking to them, they are looking to us.

Second, they recognize that with some exceptions most of those major countries do not have a viable research industry and they are very envious of that, because it's a high tech industry that they would all like to attract. Therefore, they are changing their ways.

Mr. MOSSINGHOFF. Congressman, as I have indicated in my prepared statement, the International Trade Commission did a major study of our industry in 1991 and they concluded that the enact-



ment of cost containment programs, price controls, or both, on a national level often results in decreased levels of R&D spending in that these programs reduce revenues that could be reinvested in R&D programs. Several countries that have implemented such programs have seen their pharmaceutical industries weaken or shift outside their borders. A classic case is France, which used to have one of the most innovative industries in the world. I think they are beginning to regret what they have done to their industry there.

There is a move in the European Commission as an industrial policy move to say that we really ought to back away from this. One, they are not working, and two, they are hurting local European industry.

Mr. UPTON. Thank you.

Mr. WAXMAN. Thank you, Mr. Upton.

Mr. Pallone.

Mr. PALLONE. Thank you, Mr. Chairman.

I wanted to start out by sort of reiterating what Mr. Upton said, about my concern also about price controls and the effect that they would have on the pharmaceutical industry. In Washington a lot of people have been quick to dismiss the industry's attempts to control prices, but the reality is that efforts to decrease prices, the cut-backs in the government programs to pay for certain pharmaceuticals, the new competitive enforcement for prescription drug sales really has started to take a toll on the industry.

In my home State of New Jersey—I see the Chairman and CEO of Merck is here, which is one of the New Jersey-based companies—we have really had stagnation in the industry. It has hit hard. A lot of jobs have been lost or moved out of the State.

I just want to be careful that whatever we do, whether it's price controls or a specter of it or something, however we affect the industry, that it not be something that really negatively impacts the number of jobs and hurts the industry, because that has an impact on the economy.

I came late and I know there has been some discussion about this new breakthrough drug council. If I ask something that has already been asked, you have to forgive me.

I wanted to ask one question, if we could clarify the breakthrough drug council. I understand the council has the power to review the prices of new drugs and report on their reasonableness. It's my understanding that the Secretary already has the authority to study the prices of new drugs.

I guess what I am asking is, with this new council, are we creating anything new? It seems that the council really doesn't have any new authority over the private sector, so why do we need the council?

One of the reasons I am asking that is because I understand that just the specter of the council has created problems, particularly with the biotech industries and their ability to raise capital. Some of the people have been in to see me about that.

If any of you would be willing to clarify, first, whether you see this council as having any purpose. My understanding is the Secretary already has whatever power the council would have to deal with the issue.



Mr. MOSSINGHOFF. Congressman, I think you are exactly right. I spent a long time in the government and generally the Federal Government can study anything that the Secretary decides they want to study. But what you would have here, I think, is the specter of real price regulations, the specter of a real public utility. If you have a council, you are going to have a staff, lawyers, auditors, pricing experts. You are going to put in place an infrastructure, and I think that is what the investors see. You would put in place an infrastructure which this year can only ridicule a drug price as being excessive. Next year, with a very small change, they'd just say it's not reimbursable across the line. So it's a slippery slope you step on, I think, towards a public utility type operation for the industry.

Mr. PALLONE. But you agree that there really isn't any power in this council that we don't already have through the Secretary's office or whatever?

Mr. MOSSINGHOFF. I believe the Secretary of HHS and this organization of Health Policy and Research can study almost anything they would like to study.

Mr. PALLONE. Do you have any suggestions in terms of an alternative to the council? I guess the problem has been that the fact that the council exists leads a lot of people within the industry to fear that there are going to be additional regulations and powers.

Mr. VAGELOS. It's a very inhibiting, negative thing to have a council which is going to make a decision on a product that comes out perhaps 10 or 15 years after you begin an enormous investment in a very risky project. So it would inhibit the beginning of important, risky long-term research investment.

Mr. PALLONE. Obviously there is a concern that there needs to be some vehicle. Have you thought about anything in lieu of the council?

Mr. RAAB. I would like to comment. I think there is an opportunity for the government to provide information and guidance to the providers. Again, I think it's physicians who should be making decisions on the best care of their patients, and I think everybody in this country that I've ever talked to feels that way.

As we do in our published clinical work, as the communications we have with physicians, I think there are opportunities to study various alternatives, not just breakthrough drugs, but surgery, diagnostic techniques, utilization of instrumentation, comparison of different types of drugs. I think there are opportunities to do technology studies, outcomes research, but not just limiting to any one type of therapy.

Mr. SANDERS. If I could just add one comment. You weren't here Congressman, but the breakthrough drug category accounts for only 1/500 of the total health care bill in the United States. So we are giving it an excessive prominence in terms of this particular bill only because it has the potential to cast a very long shadow in terms of our research strategy and hunkering down and taking a very conservative approach to research, which will not yield the breakthrough drugs that we are looking for.

Mr. PALLONE. Thank you, Mr. Chairman. I guess my point is simply if it doesn't have any new authority but it's causing you

problems in terms of the specter of something that is not real, maybe we shouldn't have it. We need to look at it more. Thank you.

Mr. WAXMAN. Thank you, Mr. Pallone.

Mr. Greenwood.

Mr. GREENWOOD. Thank you, Mr. Chairman.

Last month the Bureau of Labor Statistics reported that the producer price index measuring inflation for pharmaceuticals declined from 6.4 percent in 1992 to 3.1 percent in 1993, a drop of more than half.

I would like to ask, Mr. Mossinghoff, to what do you attribute that development?

Mr. MOSSINGHOFF. I think it's clear it is two things that are coming into play. First are the market forces that we have already had testimony on this afternoon that there really is a sharp, competitive, price conscious market out there that the companies must deal with. That is permanent. Try as they will, the CEO's at this table aren't going to change that situation. That is built into the structure right now.

Second, I think the decision of 18 companies to announce, and many other companies are following it without announcements, to limit their price increases to the general inflation as measured by the Consumer Price Index is having an effect. That was a decision made. Merck was the first in the industry to do that. Eighteen have now indicated that they would hold their price increases to general inflation. General inflation, I think, last year was 2.7, which was better than the blue chip prediction going into 1993. The blue chip prediction going in was 3.2, and as you indicated, we were 3.1.

Mr. GREENWOOD. A question for anyone who would care to answer it. Looking around the globe, where else besides the United States has there been major innovation in pharmaceuticals and what are the environments that have either thwarted innovation or caused there to be significant developments?

Mr. SANDERS. I think Europe and Japan have been the major sources of innovation outside of the United States. The one thing that is putting pressure upon their research programs and the Japanese companies are beginning to have great difficulty is the fact that they have had price controls and ratcheting down, if you will, of the prices of the drugs that they are selling so that they are unable to sustain their R&D programs.

I would argue that price controls have been a real factor in terms of weakening the research programs and the innovation in those particular countries, and I don't want to see that happen here.

Mr. RAAB. I would just point out that on a relative basis there is an inconsequential amount of research done in large molecules, commonly referred to as biotechnology, outside of the United States. There are a few companies in Europe, none that I know of in Japan. Again, this has happened in this country because of the opportunities investors, scientists, entrepreneurs believe our system and our science and the human resources we have in this country provide.

Mr. VAGELOS. Mr. Greenwood, let me just add one thing. As I mentioned earlier, the 3.1 percent increase in prices that was reported for 1993 really does not reflect what is happening in the

marketplace, and that is deep discounting below that to managed care. This year the managed care for Merck took 50 percent of our business. Each year it will increase. By the year 2000 I would not be surprised if it was 100 percent. With that is deep discounting, and that will reflect itself in the price increases that can be promoted.

So the market is really taking care of the problem. There almost is not a price problem today in the United States. If one looks to see how many of us are recovering the rate of inflation by price increases, we are not. I will tell you that.

Mr. GREENWOOD. Thank you, Mr. Chairman. I yield back the balance of my time.

Mr. WAXMAN. Thank you, Mr. Greenwood.

Let me ask you this. Maybe I should direct this to Dr. Vagelos. It's hard for me to believe that we have drugs that are now on the market, new drugs, within the last 2 or 3 years—Foscavir, \$21,000, Betaseron, \$10,000, Taxol, \$10,000, Ceredase, \$100,000 to \$300,000, and on and on for not a tremendously long list, but nevertheless a significant list of new drugs. You say that the market will work to hold down the price, but these are drugs for which there is a patent and they are unique. The patients have to get this drug. It's a tremendous benefit to them.

If the government is going to pay for these drugs for everybody, then the government is going to pay whatever price the manufacturers ask for. Why not \$20,000? Why not \$30,000? Why not \$40,000? If there is a government payor, we know that there are lots of folks who will come out and ask to be paid. If we don't have any kind of review of the reasonableness of the price, wouldn't you expect that there would just be unlimited payment for these drugs?

Mr. VAGELOS. I wouldn't expect unreasonable payment. First of all, I think one has to look at the price of the disease. Foscavir is for cytomegaloviral infection by HIV, which causes blindness otherwise, and there is no other drug that will do what it does. It is very expensive.

Mr. WAXMAN. Yes, but these are very important drugs. They are unique. You can't go down the street and get another drug. You need that drug. If the government is now going to pay for drugs for everybody in this country who are on the Medicare program or we are going to have this as a benefit for the private insurance sector, all that the Clinton proposal suggested is that there should be this advisory council that will examine the reasonableness of new drugs as they are launched in the marketplace. They don't put controls on the prices; they simply ask to look at the reasonableness of that price. Mr. Mossinghoff said that's going to be chilling—or maybe you made the statement—it's going to inhibit decisions. When you can look down the road and make a drug that you are going to get these kinds of prices for—

Mr. VAGELOS. Not Merck.

Mr. WAXMAN. Pardon.

Mr. VAGELOS. Not Merck.

Mr. WAXMAN. Any of you. Maybe Dr. Sanders or Mr. Raab.

Mr. RAAB. Let me make a comment. Mr. Chairman, you have mentioned this and I think there is one thing that I would like to add to the comments that have been made. You mentioned



Betaseron. There is a competitor that should be on the market to Betaseron very soon. You mentioned Ceredase. There are many companies working on solutions, other products for Gaucher's disease. Cystic fibrosis and multiple sclerosis. There is a tremendous amount of work going on in gene therapy. So it's stimulating new products.

Mr. WAXMAN. Because I have a limited period of time, I really want to move this along. The point I'm trying to make is I am challenging your statements. I am challenging your statements, because it seems to me if you are looking down the road and trying to make investment decisions in your company and don't find these drugs tremendously attractive to find some ways to produce, you would be missing out on some very, very big blockbusters.

No one wants to keep you from getting a pretty sizable return, but at some point, if they are going to be paid for, then we ought to be able to have at least a council look at the reasonableness. Or, I believe, quite frankly, if there is NIH funding in developing these drugs, as there was in the case of Ceredase, which is a \$300,000 drug—the NIH financed most of the research and clinical trials on the drug—the government that paid for all of that at least ought to have the say over that drug being priced in a reasonable manner.

I just want to make that statement to challenge you.

Let me ask you this on Medicare. If you oppose Medicare rebates, you oppose the idea of the Secretary being able to refuse to reimburse for a new drug that is priced at an unreasonable level, why don't we just go to a single Medicare formulary and replace the provisions in this bill?

Dr. Vagelos.

Mr. VAGELOS. I'm sorry.

Mr. WAXMAN. Why not just have a formulary for the Medicare program?

Mr. VAGELOS. I think I would prefer to have a market-based competitive system where different companies can come in and make bids, as we described earlier.

Mr. WAXMAN. You would want to do it on a smaller group but have it for Medicare?

Mr. VAGELOS. Exactly.

Mr. WAXMAN. What is Dr. Sanders' reaction to that idea?

Mr. SANDERS. What you are proposing is a national formulary. I have real concerns about a national formulary.

Mr. WAXMAN. I'm talking about for Medicare only here.

Mr. SANDERS. I understand. It's a third of the business. Under those circumstances, I think that you are empowering a single board with a tremendous amount of authority to determine health care for the Medicare population. I would argue that what you really want to do, as a physician myself, is to put the decisionmaking power for dispensing drugs as close to the patient as possible and not put it resident in some national health formulary board.

Mr. WAXMAN. Would you think the alliances or some—

Mr. SANDERS. I think the AHP's would be able to do that, or some variation thereof.



Mr. WAXMAN. Do you think that there ought to be some group negotiating the best deal for Medicare patients as there is for privately insured patients?

Mr. SANDERS. I have no problem with that.

Mr. VAGELOS. Exactly.

Mr. WAXMAN. I also just wanted to make a comment on these new drugs. One of my colleagues said we are going to push the research overseas. Last week I released a report showing that the drug prices in the United Kingdom are on average 60 percent less than the United States. They have a very active pharmaceutical industry. In fact, I think Glaxo is a company in the United Kingdom. What they do is they limit the profits but they exclude from consideration of the profits the amount for research and development investments.

Do you think that has worked out well? They seem to be balancing out the incentives for research and development but also making sure that their consumers are protected, and, of course, because they protect their consumers, American consumers are paying higher prices.

Mr. SANDERS. It's a complicated question, but the fact is we spent \$1.2 billion on our R&D program in 1993, \$1.4 billion in 1994. Last year we sold \$375 million in the United Kingdom. We are dealing a global marketplace and the British are benefiting from that. If we were limited strictly to the U.K. market, then we would have a much smaller research program, and who knows what the discovery process would yield.

Mr. WAXMAN. Why would you be limited to the U.K. market?

Mr. SANDERS. I said if we were just limited to the United Kingdom. I think the fact is that we do not have to deal with just a single U.K. market. It's a blend of a U.K. market, a European market, American market.

Mr. WAXMAN. I know, but that means the American market pays the higher price.

Mr. SANDERS. Yes, it does. There is no question about that. But we have rationing of health care in the United Kingdom and its citizens are accustomed to queueing there.

Mr. WAXMAN. But we are going to have rationing of health care in the United States if people can't afford to buy these drugs, which is the situation right now.

Mr. SANDERS. I think everybody should have access to health care and pharmaceuticals in the United States.

Mr. WAXMAN. I'm sorry. You think everybody in the United States has access?

Mr. SANDERS. Should have, and that's what this health care reform should provide.

Mr. WAXMAN. Dr. Vagelos, I am intrigued by your idea of these groups that would negotiate on behalf of Medicare. That just raises another question I wanted to ask of you. Many of us were intrigued by the merger of Merck and Medco. Can you tell us how this merger will affect efforts to hold down costs of prescription drugs as you see it in this new kind of market in the future?

Mr. VAGELOS. I really spoke for a pharmacy benefits management group, but I think putting together Merck and a pharmacy benefits management group such as Medco allows us to go from

basic research to production to interacting with the plan payors who will cover a greater and greater percent of the U.S. population in time and use the information that we collect. Every prescription that is filled within the company is captured as information and is used to do outcome studies and drug utilization reviews and be sure that the drugs are optimized.

We think that the program will optimize the use of drugs, optimize the outcomes, come out with the outcome studies that Mr. Wyden is so interested in to some degree, and also the competition that is engendered to get into the PBM's to the manufacturing suppliers will force down costs, and therefore you will have improved outcomes in use of the drugs, better use of drugs, and better costs.

Mr. WAXMAN. I thank you for your presentation and your patience. You've been here a long time answering a lot of questions. This is an important issue for all of us to understand as best we can and to make the right decisions for the future of your industry and for the future of the American consumers who look forward to new breakthroughs but also want to be able to purchase what is already out there too. Thank you for being with us.

Mr. Wyden, I thought I was the only one here.

Mr. WYDEN. Thank you, Mr. Chairman. I have got two brief questions.

Mr. Raab, just so we are clear with respect to this idea of competing managed pharmacy companies with Medicare, I think there is considerable merit in the concept. I've watched the Medicare part B carriers since my days with the Gray Panthers. I think you all might be able to do it better. Are you all developing a proposal in this area that you are going to give this subcommittee?

Mr. RAAB. Yes, we are.

Mr. WYDEN. When can we expect to see that?

Mr. MOSSINGHOFF. Mr. Chairman, we have obviously the Dr. Vagelos proposal and several other companies'. We are going to try to count down to a meeting of the executive committee on the 23rd of February. So we'll get with you right after that.

Mr. RAAB. And we in biotechnology are also doing something along that line and you should have it in the near future.

Mr. WYDEN. One last question for you, Mr. Sanders, and that's a question of whether we can learn from the Medicaid rebate program. I and others on this subcommittee were very interested in it. I'm concerned that the rebates in the current Medicaid program and the proposed Medicare program will provide specific and irresistible incentives to eliminate the deepest discounts in the marketplace. The best price mechanism in the otherwise successful Medicaid law has already reduced the drug price discounts by about a third, from about a 33 percent discount to about a 23 percent discount.

If you corrected this flaw and, say, went to a flat rebate of maybe 24 or 25 percent, we might save Medicaid about \$1 billion or more and also prevent lost savings in Medicare.

What would you think of that idea?

Mr. SANDERS. I'd have to study that, Congressman. I was an opponent of best price because I thought it would yield considerable perturbations in the marketplace in terms of price rises and prod-

ucts that were beyond the 25 percent rebate that was mandated in the first year.

As a policy, I think I would prefer to see the marketplace try to work in terms of competing programs from competing pharmacy benefit management companies in providing a benefit to a Medicaid or a Medicare, because I think that's the best way to introduce competition in the market. I think once you institutionalize a rebate, that's what you are going to have from now on. I think it would be better from a policy point of view to encourage the marketplace to work.

Mr. WYDEN. I am very interested, as you heard from the previous question, in looking at your idea of competing managed pharmacy companies, but the Medicaid law has been very successful. We have squeezed a lot of money out to help poor people across this country. You've heard me all this afternoon say I'm interested in incentives so that we can start encoding some of your clinical and economic information, and maybe this competing pharmacy management proposal is the way to go. But a lot of us are not going to throw this Medicaid rebate out the window either, because it has meant a lot to poor people. We will look for your proposal on the competing managed pharmacy companies.

Mr. SANDERS. Thank you, Congressman.

Mr. VAGELOS. Mr. Wyden, the best of all worlds in my view would be for Medicaid and Medicare to end up in the accountable health plans so that there are smaller regions than a national market for which people could compete with PBM type arrangements. I think that would be a very good thing. Everybody would be anxious to compete for that. And I think there would probably be better rebates than are available in Medicaid today.

Mr. SANDERS. I would certainly agree with that. I think that in terms of dealing with the Medicare cost problem that the greatest hope would be to fold it entirely into the managed competition approach.

Mr. RAAB. I think competition in the end is what we are saying. Whether it is on the cost of delivery of drugs, whether it's discovery of drugs, the more intense the competition, the better the results are going to be, and I think we have demonstrated that in this country over and over again.

Mr. WYDEN. I will just leave you with one thought. I've been pretty tough on your industry all through the 1980's, and frankly, I think at the end of 1980's we started to see the buyers get more price sensitive, but we are going into a very different period. If you are going to look at managed competing pharmacies, for example, if you are going to look at a drug price in a review board, you all are going to have to earn with specific kinds of findings, such as cost-effectiveness, you are saving people money, clinical superiority, you are going to have to earn the right for some of this regulatory relief that you are talking about. We'll look forward to seeing your proposals.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Wyden.

My thanks again.

The witnesses on the fourth panel are Albert Carver, Director of Pharmaceutical Operations, Kaiser Foundation Health Plan, Rob-



ert Marshall, CEO, California Pharmacists Association, and Ronald Ziegler, representing the Community Retail Pharmacy Health Care Reform Coalition.

We are pleased to welcome you to our hearing today. Your prepared statements will be in the record. We would like to ask you to limit the oral presentation to no more than 5 minutes.

Mr. Carver.

**STATEMENTS OF ALBERT L. CARVER, DIRECTOR OF PHARMACY OPERATIONS, SOUTHERN CALIFORNIA REGION, KAISER PERMANENTE MEDICAL CARE PROGRAM; ROBERT P. MARSHALL, CEO, CALIFORNIA PHARMACISTS ASSOCIATION; AND RONALD L. ZIEGLER, PRESIDENT, NATIONAL ASSOCIATION OF CHAIN DRUG STORES, ON BEHALF OF THE COMMUNITY RETAIL PHARMACY HEALTH CARE REFORM COALITION**

Mr. CARVER. Thank you, Mr. Chairman and committee members. I am Albert Carver, Director of Pharmacy Services for the Southern California Region of the Kaiser Permanente Medical Care Program. I represent a number of managed care organizations, hospitals and long term care providers here, which are listed in my written testimony.

While our organizations have differing views on whether there should or should not be a free-standing Medicare drug benefit, we all have valuable experience in the market for buying prescription drugs.

I would like to discuss two important issues here today.

First, if we assume there is to be a free-standing Medicare drug benefit financed by a rebate program, should the rebate program operate similarly to the Medicaid best price program?

Second, is there any need for a provision in the law to restrict the terms under which drug manufacturers may provide discounts to prudent purchasers?

On the rebate issue, our experience indicates that the proposed rebate formula would cripple organizations that have been able to negotiate discounts. The structure of the rebate is merely a slight variation on the Medicaid best price scheme. Like best price, it is an attempt to piggy-back on the private sector discounting to define the level of rebates, and like best price, the proposal would create incentives for manufacturers to discontinue discounts to prudent purchasers.

In fact, the Medicare rebate formula would create an even stronger incentive to discontinue discounts than Medicaid. Not only is the Medicare outpatient drug market roughly three times the size of Medicaid, but the weighted average formula of the Medicare rebates would encourage manufacturers to reassess all their discounts, not just their deepest discounts.

Kaiser has already seen first hand the effects of the best price formula. Kaiser was a participant in last year's GAO report on the effects of OBRA 90. Where Kaiser had no contracts for the drugs studied, average drug price increases went from 4.7 percent the year before OBRA to 7.7 percent the year after OBRA. For those drugs where Kaiser had a contract that expired during the study



period, average price increases rose from 3.5 percent the year before OBRA to 52 percent the year after OBRA.

We strongly recommend that if a rebate mechanism is established for the Medicare program the rebate formula be based on a flat percentage of AMP, as Congress adopted in the Veterans Health Care Act last year. Why repeat past mistakes?

The administration's bill would also sharply limit manufacturers' flexibility in discounting. And this is beyond just Medicare purchases. It would apply to the sale of all outpatient prescription drugs in the United States. The provision lists, and would therefore limit, the reasons why a discount may be granted. It would be difficult for manufacturers to justify a discount solely because it believes that a purchaser has the ability to move market share. Dr. Lee addressed this briefly this morning.

But let me describe how Kaiser works to move market share. Through close collaboration between physicians and pharmacists in our organization, we evaluate the many available treatment options and recommend only those with the most benefit to our patients. These recommendations are based on extensive review of the medical literature, manufacturers information, and the clinical experience and judgment of practicing physicians. The recommendations we adopt are recorded in a document known as the formulary.

But making formulary decisions is only the beginning of a very organized process to appropriately manage drug utilization. Physicians receive continual education concerning appropriate drug use through lectures, one-on-one visits, and printed media. Experts from multiple clinical disciplines develop treatment guidelines for particular diseases.

We also monitor the effect of our efforts to influence drug usage. We routinely collect and report drug utilization back to physicians regarding their prescribing decisions. Physician specialty groups review compliance with guidelines. Where appropriate, research is conducted to insure that patient outcomes have been favorable.

This whole effort maximizes our leverage at the bargaining table with the pharmaceutical manufacturers. The results of this process has certainly given us the ability to move market share of individual pharmaceutical products. Manufacturers have responded to it in their pricing. As a result, manufacturers can't price their drugs at will to us anymore.

Importantly, however, it is practically impossible to quantify the extent to which any one of the steps in our process results in what proportion of our total discounts, as the administration bill would require. All of these benefits may come to a crashing halt as soon as the equal access provision changes the current law regarding discriminatory pricing, which is now well established under the Robinson-Patman Act. This new standard, if adopted, may unleash a torrent of lawsuits challenging manufacturers' discounted pricing policies, which we believe could result in manufacturers abandoning all discounts. This will occur because enforcement of the equal access provision would require manufacturers to open their books to HCFA, which they will seek to avoid by adopting a single price policy.

We believe that the market has began at last to work for the purchase of prescription drugs. Let's not throw away what does work. Allow us to continue to bring the manufacturers to the bargaining table and negotiate competitive prices.

Thank you for considering our views. I will respond to your questions later.

Mr. WAXMAN. Thank you very much, Mr. Carver.

[The prepared statement of Mr. Carver follows:]

**Testimony of Albert L. Carver  
Director of Pharmacy Operations  
Southern California Region - Kaiser Permanente Medical Care Program**

Before the Subcommittee on Health and the Environment  
House Energy and Commerce Committee

February 8, 1994

**I. INTRODUCTION**

Mr. Chairman and Members, I am Albert L. Carver, Director of Pharmacy Services for the Southern California Region of the Kaiser Permanente Medical Care Program. I am representing a number of managed care organizations and representatives of hospital and long term care providers, including the American Hospital Association, AmeriNet, American Healthcare Systems, the American Society of Consultant Pharmacists, the Federation of American Health Systems, FHP Health Care, Group Health Association of America, the Health Industry Group Purchasing Association, the Health Insurance Plan of Greater New York, Voluntary Hospitals of America, and others. While our organizations have differing views on whether there should or should not be a free-standing Medicare drug benefit<sup>1</sup>, we all have valuable experience in the market for buying prescription drugs. We thank you for the opportunity to share the insights we have gained as large, well organized purchasers in the prescription drug market.

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<sup>1</sup> The American Hospital Association, AmeriNet, American Healthcare Systems, the Federation of American Health Systems, the Health Industry Group Purchasing Organization and Voluntary Hospitals of America all believe that, in general, Medicare should be incorporated into the main health care system. It is the belief of these organizations that Medicare beneficiaries should be encouraged to enroll in accountable health plans in the new system and that the Medicare drug benefit should be provided as an incentive for them to do so. They believe that this would lead to the gradual incorporation of Medicare beneficiaries into the mainstream of the health care delivery system.

These insights are very important to apply to two relatively narrow issues -- (1) if there is to be a free-standing Medicare drug benefit financed by a rebate program, should the rebate program operate similarly to the Medicaid so-called "best price" program? and (2) is there any need for a provision in the law to restrict the terms under which drug manufacturers may provide discounts to purchasers who are able to negotiate those discounts?

## II. MEDICARE REBATES -- THE LESSON OF MEDICAID "BEST PRICE"

The rebate formula provided in the Administration's plan would have a severe impact on the ability of organizations that have historically been able to negotiate discounts from drug manufacturers. The requirement that rebates be 17 percent or the difference between the average manufacturer's price ("AMP") and the weighted average of all discounted prices offered to non-retail buyers is merely a slight variation on the Medicaid "best price" scheme, an attempt to piggy-back on private sector discounts to define the level of Medicare rebates.

Like the Medicaid rebate program, the proposal would create incentives for manufacturers to discontinue or modify discounts to prudent purchasers. Indeed, the Medicare rebate formula would create an even stronger incentive to discontinue discounts than does the Medicaid "best price" requirement. Not only is the Medicare Part B outpatient drug market roughly three times the Medicaid market (35-40 percent, compared to 13-14 percent), but the weighted average formula would encourage manufacturers to reassess ALL their discounts, not just their deepest discounts.



Kaiser has already seen first hand the affects of the Medicaid "best price" formula. Kaiser Permanente was a participant in last year's GAO report on the effects of the OBRA provision. Where Kaiser had no contracts for the drugs studied, average drug price increases went from 4.7% the year before OBRA to 7.7% the year after OBRA. For those drugs where Kaiser had a contract that expired during the study period, average prices rose from 3.5% the year before OBRA to 52% the year after OBRA.

Of course, this proposal will hurt not only large provider organizations receiving discounts, but ones that receive smaller discounts as well -- including those under 17 percent. For every discount a manufacturer offers to a very hard-bargaining purchaser over 17 percent off of AMP, the manufacturer will look to other discounts from weaker purchasers, such as small buying groups, new retail buying groups and others to make up the difference. To the extent that they can't achieve that, they may simply refuse to offer the kind of discounts large, well organized purchasers would be able to demand but for this intrusion into the negotiating process.

We strongly recommend that if a rebate mechanism is to be established for the Medicare prescription drug benefit program, the rebate formula be based on a flat percentage of AMP, as Congressman Slattery and Senator Chafee proposed changing in the Medicaid rebate program a year and a half ago. We find it difficult to understand why a flat 17 percent was not proposed (or 15 percent, as originally suggested) when the adverse effect on private purchasers of the Medicaid "best price" has become so well

known to policymakers in Congress and in the Administration. This subcommittee heard testimony last year as to the problems with the "best price" rebate formula. Congress responded by establishing a flat rebate program in the Veterans Health Care Act of 1992. Extension of the "best price" approach will have the same negative effects on drug pricing. Why repeat mistakes?

### III. THE "EQUAL ACCESS" PROVISION'S EFFECT ON DISCOUNTING IN THE PHARMACEUTICAL MARKET

Beyond the problem created by the rebate formula, the Administration's bill would sharply curtail manufacturer flexibility in discounting prices of their products. All manufacturers would have to promise not to discount prescription drugs to all purchasers, not just Medicare, except as specifically allowed by the Administration's bill. The problem with the so-called "equal access to discounts" provision in the Administration's bill is that it enumerates the reasons why a discount may be granted. The provision focuses on volume and cost savings realized by manufacturers. It doesn't recognize that discounts are granted based on a purchaser's ability to influence drug prescribing patterns and use in a specific population. We call this "moving market share" and manufacturers respond to it.

Let me describe how an organized drug purchasing and management program in my organization, the Southern California Region of Kaiser Permanente works to "move market share." Through close collaboration between physicians and pharmacists in our

organization, we evaluate the many available drug regimen options and recommend only those with the most benefit to our patients. These recommendations are based on extensive review of the medical literature, manufacturer's information, and the clinical experience and judgment of physicians. The recommendations we adopt are recorded in a document known as a formulary.

But making formulary decisions is only the beginning of a very organized process to appropriately manage drug utilization. Physicians receive continual education concerning appropriate drug use through lectures, one-on-one visits and printed media. Experts from multiple clinical disciplines develop treatment guidelines for particular diseases.

We also monitor the effect of our efforts to influence drug usage. Computer systems are used to routinely collect and report drug utilization data back to physicians regarding their prescribing decisions. Physician specialty groups review compliance with guidelines. Where appropriate, research is conducted to insure that patient outcomes have been favorable.

Our investment in this integrated and organized process results in the ability to concentrate utilization into a single or limited number of high quality products within a therapeutic class. This effort maximizes our leverage at the bargaining table with the pharmaceutical manufacturer. It is not possible to quantify the extent to which each of

the individual components of our process results in what proportion of our discount, but the results of this process has certainly given us the ability to "move market share" of individual pharmaceutical products, and manufacturers have responded to it.

Kaiser Permanente was one of the pioneers of this approach, but the techniques are not exclusive to HMOs. Hospitals and managed pharmaceutical benefits organizations have been able to move market share in wider populations -- manufacturers have responded by discounting to them as well. In this way, the market for pharmaceuticals has begun to work. In HMOs, hospitals and managed pharmacy, no longer are clinicians unaware of drug costs, nor are these organizations lacking in the ability to get an affordable price. Manufacturers can't price their drugs at will to us anymore.

All of these benefits may come to a crashing halt as soon as the "equal access provision" changes the current law regarding discriminatory pricing, which is now well-established under the Robinson-Patman Act. This new standard, if adopted, may unleash a torrent of lawsuits challenging manufacturer's discounted pricing policies which, we believe, could result in manufacturers abandoning all discounts. This will occur because enforcement of the "equal access" provision would require manufacturers to open their books to HCFA, which they will seek to avoid by adopting a single price policy.

We believe that the market has begun, at last, to work for the purchase of prescription drugs. Clearly there are still some problems. But let's not throw away what does work by correcting the wrong problem -- allow us to continue to bring the manufacturers to the bargaining table and negotiate competitive prices.

Thank you for considering our views. I would be happy to answer any questions you may have.



Mr. WAXMAN. Mr. Marshall.

# **STATEMENT OF ROBERT P. MARSHALL**

Mr. MARSHALL. Chairman Waxman and members of the subcommittee, I am Dr. Robert Marshall, Chief Executive Officer of the California Pharmacists Association, representing in excess of 6,500 pharmacy professionals in California.

We appreciate the opportunity to present testimony on the pharmacy component of the Health Security Act. Our association joins our two national association coalitions in endorsing many areas of the Act. However, we do notice the need for some changes in specific areas of the plan.

All of us are familiar with the problems of increasing costs and increasing number of uninsured people. We know that universal access to health care is imperative for any industrial nation to prosper.

The question becomes, therefore, how the delivery of cost-effective, accessible health care will be defined and implemented. In order to help you define these optimal health care parameters, California Pharmacists Association provides the following comments concerning the issue of access.

Access to pharmaceutical care can be viewed in two distinct areas: pharmacy provider networks and consumer choice.

As President Clinton's proposal is currently drafted, regional health plans would be required to provide pharmaceutical benefits but would be allowed to limit the number and type of participating pharmacy providers that would be included. The health plan could require enrollees to obtain pharmacy services from certain providers exclusively authorized by the health plan. The health plans would also be able to establish different payment rates for those inside the networks and those outside the networks and to use single source suppliers for pharmacy and medical equipment.

These limitations would create false economies via the myth that the best rates can only be achieved by limiting the provider network. This myth is based on a principle of exclusive contracting that works for hospital care but does not for pharmacy. Pharmacists have historically been presented contracts with take it or leave it terms rather than negotiated rates, and most pharmacies have accepted even below cost reimbursement rather than disrupt the relationship between them and their patients.

Universal access to pharmaceutical products and pharmacists' services must be among the highest priorities in any reform system. Pharmacists' services have proved to be among the most cost-effective aspects of health care delivery, addressing health care needs both proactively and retroactively.

Properly combined as total pharmaceutical care, pharmaceutical products and pharmacists' services improve a patient's quality of life and lower overall health care costs by minimizing the need for costlier more intensive services.

The community pharmacist is the most accessible member of the health care team. A properly functioning open network of pharmacists and pharmacies contributes immeasurably to cost avoidance just by being there where and when needed. Pharmacists provide such services as patient consultation to inform patients about

appropriate medical use, monitoring of patient records to identify and prevent adverse reactions, as well as making determinations based on drug use as to whether patients should seek additional care. Oftentimes the recommendation of a relatively simple non-prescription product can prevent a condition from developing to a point where additional health services become necessary.

These services have proved to be eminently cost-effective. A recent project of the American Pharmaceutical Association identified over 300 specific articles which demonstrated the value of pharmaceutical care. The benefits of patient education by pharmacists to the physical health of the beneficiaries and the physical health of any health plan are well documented and significant.

Attempts to restrict beneficiary access to exclusive pharmacy networks such as independents only, chains only, mail order create confusion and inconvenience for patients and animosity among pharmacies, physicians and patients alike. Such limits must be and can be avoided by maintenance of broad, open pharmacy networks.

An open pharmacy network should include a variety of specialty pharmacies and unique pharmacy services needed, including medical supply pharmacies, long-term care, home health and infusion therapy, and compounding specialists. Most community pharmacies provide 24-hour emergency services and home delivery. All contribute to keeping patients out of the hospital emergency clinic for non-emergency care.

Anything less than open pharmacy networks will increase costs due to patients seeking alternative resources such as treatment in emergency rooms or admission to in-patient services.

Additionally, exclusive provider networks, pharmacy networks can eventually severely limit the number of potential competitors and henceforth lower quality service which can be provided by those exclusive providers with very little risk of losing business.

Open pharmacy networks do not have to be expensive. During 1992 pharmacy reimbursement in a large open pharmacy network sponsored by a California drug benefit plan administrator, Pharmaceutical Care Network, averaged \$8.90 per member per month. This compares favorably to the average expenditures of \$9.74 for HMO's reported by a 1992 survey, and only staff model HMO's reported lower expenditures, at \$8.44 per member per month.

Employing open networks does not prevent the use of differential co-pays for differential levels of services. Increased cost sharing by patients can also help control utilization, a major cause of increasing costs. Patient access to all pharmacies which are willing to participate will not significantly increase administrative costs but does assure that patients get needed medications safely and in a timely fashion as well as face-to-face consultative services, drug use monitoring and outcome measurement.

I have additional testimony in my written comments, which includes remarks on total pharmaceutical care services, medication formularies, case management, generic usage, prior authorization and drug utilization review.

Thank you.

Mr. WAXMAN. Thank you very much, Mr. Marshall.

[Testimony resumes on p. 757.]

[The prepared statement of Mr. Marshall follows:]

**Comments of Robert P. Marshall, PharmD, CEO  
California Pharmacists Association  
on  
President Clinton's Proposed Health Security Act  
to the  
House Subcommittee on Health and the Environment  
February 8, 1994**

Chairman Waxman and members of the Subcommittee, I am Dr. Robert Marshall, Chief Executive Officer of the California Pharmacists Association. The California Pharmacists Association is the nation's largest state association of pharmacists representing in excess of 6,500 pharmacy professionals and associates. The 190,000 pharmacists licensed in the United States represent the nation's third largest health profession.

Thank you for the opportunity to present testimony on the pharmacy component of President Clinton's Health Security Act. The California Pharmacists Association joins the NARD/NACDS' Community Retail Pharmacy Health Care Reform Coalition and the five national pharmacy associations' Coalition for Consumer Access to Pharmaceutical Care in endorsing many areas of the Act. However, we do notice the need for changes in some specific areas of the plan.

The need for national health care reform is undeniable. In 1992, 14% of the Gross National Product--about \$838.5 billion--was spent on health care. In 1991, \$216.7 billion was spent on Medicare/Medicaid (9% of all government spending), and yet 35 million Americans were and are left uninsured. Our citizens recognize the need for reform, President Clinton obviously recognizes the need, and Congress clearly understands that universal access to health care is an imperative for any industrialized nation to prosper.

The question becomes, therefore, not whether health care reform is necessary, but rather how delivery of cost-effective, accessible, high quality health care will be defined and implemented into the next decade and beyond. Clear



parameters are necessary in order to maximize the potential of health care reform in the United States. In order to help you define these parameters, the California Pharmacists Association has provided the following comments identifying areas of concern to the pharmacy profession.

Access to pharmaceutical care can be viewed in two distinct areas--**provider networks** and **consumer choice**. It is these issues that are of concern to CPhA's membership.

As the proposal is currently drafted, regional health plans would be required to provide drug benefits but would be allowed to limit the number and type of participating pharmacy providers in a variety of ways. The health plans could require enrollees to obtain health services from certain pharmacy providers exclusively authorized by the health plan. The health plans would also be allowed to establish different payment rates for participating health providers and those outside the network and to use single-source suppliers for pharmacy, medical equipment, and other health products and services. These limitations would create false economics via the myth that best prices can only be achieved by limiting the provider network. This myth is based on a principle that works for hospital care by the reduction of costs associated with excess capacity. These reduced costs are achieved by using negotiated rates and exclusive contracts to concentrate provider services. However, pharmacy is not the same. Pharmacists have historically been presented contracts with "take it or leave it" terms rather than negotiated rates.

Universal access to quality health care, which includes pharmaceutical products and pharmacists' services, must be among the highest priorities in any reformed health care system. Indeed, pharmacists' services have been proved to be among the most cost effective aspects of quality health care delivered to our population, addressing health care needs both proactively and reactively. Properly combined as **total pharmaceutical care**, pharmaceutical products and pharmacists' services improve a patient's quality of life and lower overall health care costs by minimizing the need for costlier services, such as unnecessary physician visits, emergency room visits, hospitalizations, and long term care admissions and stays.



Pharmacists are not simply purveyors of pills and potions, but highly educated and qualified medical professionals. It is widely recognized that the community pharmacist is the most accessible member of the health care team. A properly functioning open network of pharmacists/pharmacies will contribute immeasurably to cost avoidance by *being there*, where and when needed.

Pharmacists can and do provide such services as patient consultation to inform patients about appropriate medication use and side effects, monitoring of patient records to identify and prevent possible drug/drug or drug/food interactions, as well as making determinations based on drug use and outcomes as to whether a patient should seek additional care. Oftentimes recommendation of a relatively simple non-prescription product can prevent a condition from developing to a point where additional physician visits, emergency room visits, or hospital admissions will become necessary. These "cognitive services" have been proved to be eminently cost effective, appropriate and efficient for today's health care environment. A recent project of the American Pharmaceutical Association identified 300 scientific articles which demonstrate the value of pharmaceutical care. Identification of and intervention for drugs improperly used and drugs not used even when available are part of the daily routine of problems encountered by pharmacists. The benefits of patient education by community pharmacists to the physical health of the beneficiaries and the fiscal health of any health plan are well documented and significant. Attempts to restrict beneficiary access to special outlets such as limited or "exclusive" pharmacy networks, hospital outpatient dispensaries, "independents only" or "chains only" create confusion and inconvenience for patients, and animosity among pharmacies, physicians and patients alike. Such limits must be and can be avoided by establishment of broad open pharmacy networks.

A good open pharmacy network should include the variety of specialty pharmacies and unique pharmacy services needed and currently provided to assure continuing appropriate patient access. Included should be medical supply specialty pharmacies, long term care services pharmacies, home health care and home infusion therapy pharmacies, and drug compounding specialists. Community pharmacies provide emergency and late hour or 24 hour services and home delivery. All contribute to keeping patients out of the hospital emergency clinic for non-emergency care. No one type of pharmacy or limited network can adequately replace the full scope of services available today. The

existing pharmacy network meets these requirements. Anything less will not. Anything less will increase costs due to patients' seeking out costly alternative resources such as treatment in emergency rooms or requiring admission to inpatient status for services which can be safely and effectively provided in lower levels of care such as home care or long term care.

Additionally, exclusive pharmacy networks can eventually severely limit the number of potential competitors. When patients have limited choices, lower quality service may be provided with less risk to the plan of losing business. Extremely low reimbursement rates also create a disincentive to the exclusive pharmacy network provider for working with the health delivery system to contain costs by increasing the rate of generic or alternative drug use, to counsel patients and to educate physicians about cost-effective prescribing.

"Open" pharmacy networks do not have to be expensive. During 1992, pharmacy reimbursement in the large "open" pharmacy network sponsored by a California drug benefit plan administrator, Pharmaceutical Care Network, averaged \$8.90 per member per month. This compares favorably to the average expenditures of \$9.74 for health maintenance organizations reported by the 1992 Managed Care Prescription Drug Therapeutic Class Survey. Only staff-model HMOs reported lower expenditures, at \$8.44 per member per month. Also, the high level of willingness of patients to pay more in cost-sharing for increased access to their choice of pharmacist can negate slight cost differences in reimbursement between a standard open and an extremely restrictive pharmacy network. "Any willing provider" supportive legislation also does not prevent the use of different co-payments for different levels of services. Increased cost sharing by patients also can help control utilization, a major cause of increasing costs.

Further, patient access to all pharmacies which are willing to participate will not significantly add administrative expense. Such open pharmacy provider access for patients does, however, assure that patients can get needed medications in a timely fashion, rather than making additional visits to physician's offices and clinics, emergency rooms and hospitals, all of which add costs and treatment delays. The patient has the opportunity to receive from the pharmacist the value added face-to-face consultative services, drug use profile review and monitoring.

and drug therapy outcome measurement. Again, these cognitive services have demonstrated significant value in preventing and dealing with drug therapy misadventures due to improper drug usage and multiple sources of drug prescribing. Realistically, these value-added services are not economically feasible if the drug product is the only element of total pharmaceutical care the health delivery system is willing to provide. Neither would these value added services prove logistically possible if the provision of pharmacists' services is overly concentrated into a minimum number of pharmacies.

Utilizing open pharmacy networks does not subvert the ability of health delivery systems to select and reward the most efficient providers. It may be required that all participating pharmacies agree to terms that include adequate performance standards. The process of validating adherence to standards might slightly increase administrative costs initially as a health delivery system develops its network. Maintaining the network to high level quality standards requires only minimal costs. Broad open pharmacy networks also increases true and level competition when participating pharmacies know that the system can redirect patients to better service providers.

Surveys of 6,600 consumers by California Health Decisions identified five basic conclusions regarding health delivery systems. One major conclusion was that freedom of choice continues to be essential for most people. A broad open pharmacy provider network is an important consideration for employee benefit design companies and employers, as well as the patients themselves.

By allowing "any willing pharmacy provider" to function in the national health care reform setting, Congress would create an environment which would maximize patient compliance and provide the best source for patient information dissemination. The reform package must personalize the most accessible point of contact--pharmacists.

Hand in hand with the "any willing pharmacy provider" precept is that of freedom of choice for the patient. Access is mutual, both patient to pharmacist and pharmacist to patient. Patients must be able to determine their preferred setting of pharmacy services.

Freedom of choice does not occur, for example, when a patient chooses between a managed care entity and indemnity coverage. Increasingly limited provider selection does not allow for freedom of choice when the available alternatives are either inaccessible, have limited coverages, or provide no coverage at all. In this situation, freedom of choice does not truly exist.

### **Additional Written Comments**

#### **CPHA Recommendations for Improvements to the Health Security Act**

There are seven specific pharmacy-related provisions in President Clinton's plan, and these are: prescription drugs and related benefits, the Medicare prescription benefit, equal access to pharmaceutical prices, provider networks and freedom of choice, manufacturer cost containment, antitrust reform, and integrated information systems.

Our predominant concern, as stated in Dr. Robert Marshall's remarks, is that of provider networks and freedom of choice. The pharmacists of our nation believe that an accessible, high quality, cost effective total pharmaceutical care benefit can only be attained by implementing the "any willing pharmacy provider" precept.

Pharmacy has additional concerns and recommendations related to the remainder of the pharmacy-related provisions of the proposed plan, and they are as follows:

#### ***PRESCRIPTION DRUGS AND RELATED BENEFITS***

**Utilization Control:** Numbers of prescriptions per month, formularies or other means of drug use control can and should be used to control the extent and appropriateness of medication utilization.

**State and Federal MAICs:** Existing state and federal Medicaid maximum allowable ingredient cost (MAIC) restrictions are applicable to total



pharmaceutical care programs. These wholesale price limits encourage the use of lower cost generic drugs where available and practical.

**Case Manager Approval of Prescriptions:** Some health care proposals have considered requiring the approval of the patient's primary care physician for all prescriptions issued by consultant, specialized physicians. This requirement, if applied across the board, is unwieldy and unnecessary. However, a case manager program is appropriate for home infusion therapy services. The economic rewards and assurances of therapeutic appropriateness are well proved in this latter specialty field.

**Formulary Development:** In most successful programs, formularies are developed by a local formulary committee, comprised of representatives from the Plan, and from the physician and pharmacist community. The pharmacists accross the nation are fully prepared to undertake this critical project.

**Formulary Access:** New and existing specialty drugs must be available to patients when their use is therapeutically appropriate. To assure access to such appropriate therapy, consideration must be given to receiving information from pharmaceutical manufacturers, providers and patients for additions or deletions to the formulary. This criterion is best satisfied by establishment of a local committee that acts as a contact point and clearinghouse for such information.

**Breadth of Drug Coverage:** Uniform guidelines should be developed so that the same standards of formulary inclusion and identification of preferred therapeutic agents are used in each (drug) therapeutic category. Appropriate committees must first establish an overall philosophy of drug coverage, based on available funding and therapeutic appropriateness. The goal of therapeutic equivalent interchange would be cost effective, high quality, rational therapy.

**Establishment of Prior Approval Mechanism:** Unless the health care system has determined that it will utilize a completely "open" formulary (a choice not recommended), a working and speedy mechanism for obtaining prior approval for payment for non-formulary drug use and special therapy or drug delivery systems must be developed. The pharmacists of this nation have had years of experience working with such models.

## ***TOTAL PHARMACEUTICAL CARE***

Providing encouragement and compensation to pharmacists for patient-oriented service is every bit as vital as providing drug products. The following topics illustrate some of the vital pharmaceutical care services which pharmacists provide.

**Patient Compliance:** The ability to case manage the compliance with drug therapy and to maximize the cost-effectiveness of drug therapy are within the scope of activities best assigned to the pharmacist at the local level. To illustrate the importance of this one facet of total pharmaceutical care, noncompliance with drug therapies accounts for about 10% of all hospital admissions. Charlie West, executive vice president of the National Association of Retail Druggists says "The costs of drug noncompliance in unnecessary medical interventions, hospitalizations, and nursing home admissions are staggering and, in large measure, avoidable." It is estimated that 14-21% of patients never have their prescriptions filled, and only 54% have repeat prescriptions filled, costing an estimated \$8.5 billion for increased hospital admissions and physician visits. Additionally, it is estimated that of the 1.8 billion prescriptions that are filled annually, half are not taken properly. Noncompliance is responsible for approximately 10% of all hospital admissions, 25% of all geriatric hospital admissions, and 23% of all nursing home admissions.

According to the American Pharmaceutical Association, it is estimated that expanded pharmaceutical services could save \$36 billion annually through improved patient compliance, reducing inappropriate drug use and hospitalizations, and decreasing adverse effects.

Critical to good compliance is face-to-face professional service from the pharmacist. As a total quality improvement/assurance issue, an adequate pharmacy benefit should ensure that the patient receives *individualized* counseling from the pharmacist.

**Cognitive Services:** Pharmacists provide such services as patient consultation to inform patients about medication side effects, monitoring of patient records to

prevent possible drug/drug or drug/food interactions (many of these quite serious and necessitating hospital admissions, or at the very least more complex and expensive therapies--the average cost of a prescription being just over \$24 as compared to the average cost of a one-day hospital stay at \$650, and making determinations as to whether a patient should seek additional care. Oftentimes recommendation of a relatively simple over-the-counter product can prevent a condition from developing to a point where additional physician visits, emergency room visits, or hospital admissions will become necessary. Drug interactions and adverse drug reactions account for about 7% of all hospitalizations (although the FDA has noted that reported ADRs represent only a fraction of the actual number of prescription drug-induced hospitalizations and deaths).

Geriatric patients--About 40% of geriatric patients on drug therapy experience adverse drug reactions, and although the elderly comprise only 12.5% of the population, they consume 32% of all prescription drugs. As much as one third of hospital admissions for the elderly may be the result of ADRs, and a 1983 estimated cost of these hospitalizations and subsequent treatments was \$4.5 billion.

Approximately 70% of adverse effects are predictable and preventable through pharmacist monitoring and intervention.

Medication errors--A recent study of pharmacist intervention on medication errors found that over one-fourth of medication errors identified and corrected by pharmacists could have resulted in harm to the patient. The savings as a result of these interventions was an estimated \$123 per problematic prescription.

These "cognitive services" prove eminently cost effective and efficient for today's health care environment.

**Expanded Scope of Practice:** Pharmacists are among the most highly trained of all health care professionals, and are the single most knowledgeable source on the use of pharmaceutical products. As such, they are also capable of expanded services, including but not limited to therapeutic drug equivalent interchange (the use of same drug generic substitutions or less costly therapeutically equivalent products), routine immunizations and management of

a "third class of drugs." Third class of drugs is defined as drugs available without a physician's prescription, but limited to evaluation for use and distribution by a pharmacist. Examples might be certain antibiotics, oral contraceptives and nicotine patches for assisting with smoking cessation. The savings attributable to this expanded scope of practice would be enormous in both dollars and in the freedom in time and energy it would allow other health care professionals in their daily practice.

**Cost Containment:** Because total pharmaceutical care addresses the health care needs of the American people proactively, it causes a marked decrease in the total health care cost by diminishing unnecessary physician visits, emergency room visits and hospital admissions. In the "big picture" total pharmaceutical care is probably the most accessible tool to minimizing the cost of health care. Consider the savings that might be attributable to increased patient compliance as well as minimization of adverse drug reactions and medication errors.

**Compensation for Total Pharmaceutical Care:** When developing national health care system reform, compensation for the broad spectrum of pharmacy services offered must be considered. Adequate compensation would incentivize delivery of comprehensive medication use management services like therapeutic interchange, when appropriate, and maximize efforts to improve patient compliance. Thus, rational therapeutics and positive therapeutic outcomes would be achieved. For example, there are a of number products available within the drug class of calcium channel blockers which are used for the control of hypertension. Many of these products are available generically at greatly reduced cost when compared with their brand name equivalents. Others are time-released products which cost considerably more than equivalent doses of non-time released versions. Use of the lower cost products can result in significant overall savings to the plan; however, because of marketing and detailing by the drug manufacturers, the more expensive products are generally used. This is of little consequence to the pharmacist, who is paid the same dispensing fee regardless of the particular type of product dispensed. This program will enjoy success only if a portion of the savings are passed on to the pharmacist in return for his intervention efforts, perhaps as payment for *pharmaceutical care services* as defined under current law. The scope of



savings can best be appreciated when a breakdown of the overall cost of prescription drugs is considered: an estimated 70% or more of the total money paid for prescription medication goes to cover the cost of goods. Past efforts by third party payers to decrease prescription drug outlays have traditionally focused on the 30% or less of payments which reflect dispensing fees paid to pharmacies. It is obvious that a more fertile field for cost control is to utilize the professional skills of the pharmacist to direct prescription use to products which will result in the most cost effective use of Medicaid funds. Therapeutic interchange, under protocols, is common practice in most HMO environments and especially so in inpatient hospital pharmacies as the vehicle for cost reduction ... it works.

### *INTEGRATED INFORMATION SYSTEMS*

**Administrative Efficiency/Quality Assurance:** Fully integrated health care management information systems must be created to maximize cost savings and to create and track better patient outcomes. This means that a communication system must be established among health care providers that will offer pharmacists patient-specific information, including: appropriate demographics, medical history, diagnoses, laboratory data, therapeutic goals and desired outcomes, potential drug-related problems, and any other information that might effect the patients' therapeutic regimen. In return, the pharmacist would be required to document any recommendations on potential therapeutic options that he may discern, and record all services that he/she provided to the patient.

Universal claim forms and electronic claims adjudication should be streamlined to minimize requisite paperwork for patients and pharmacists alike.

**Drug Utilization Review (DUR) and Drug Use Evaluation (DUE):** Drug Utilization Review (DUR) and Drug Use Evaluation (DUE) programs must be instituted to optimize therapy and decrease unnecessary and inappropriate care. The programs enhance the ability to improve therapeutic outcomes, protect the confidentiality of patients, and involve pharmacists in the development of clinical standards and educational interventions.

Thank you for addressing these initial health care issues, and particularly for your attention to the concerns of pharmacy. We urge you as members of Congress to see to it that these important elements of the nation's health care system's reform are included in the finalized legislation.

Thank you.

Mr. WAXMAN. Mr. Ziegler.

# STATEMENT OF RONALD L. ZIEGLER

Mr. ZIEGLER. Thank you, Mr. Chairman. I have with me Rob Waspe, our Senior Vice President of Policy. We are testifying on behalf of Community Retail Pharmacy.

We have formed a coalition with the National Association of Retail Druggist, and together we represent almost all of the 60,000 community retail pharmacies in America, and we provide pharmacy care for 90 percent of the 2 billion outpatient prescriptions dispensed each year.

Our coalition is proud to support President Clinton's health care reform initiative, because it provides private health care insurance to all Americans, including pharmacy care that does not exclude the elderly.

Today nearly 50 percent, or 16 million, of the Nation's elderly do not have prescription drug coverage. Mr. Chairman, prescription drug coverage is essential. Any health plan that provides coverage for doctors, medical tests and hospitalization but not the medicine to treat the illness is incomplete. Three out of five visits to a doctor result in a prescription. Drug therapy is on the cutting edge of health care and coverage for it should not and must not be viewed as an afterthought.

Everyone is interested in the cost of the Medicare prescription drug benefit. Certainly everyone has seen prescription prices go up. However, it has been well documented that these increases are not the result of increased profits at the neighborhood drugstore.

Community retail pharmacy net profits have remained at only 2.2 percent as prices have increased compared with manufacturer profits that have reached a high average of 16.1 percent. The increases for prescriptions at drug stores have come about because drug stores have had to continually pay the manufacturer more and more for the drugs they buy in order to have them available to the patients and consumers who visit the local drug store.

As an example, when we look back in terms of the value of today's dollar projected back over the past 20 years, pharmaceutical manufacturer prices have increased 36 percent in real dollar terms, while community retail drug store profits per prescription have decreased 36 percent.

In terms of cost of the pharmacy benefit for Medicare, we have recently commissioned two studies, one by Lewin-VHI, to determine health costs that can be avoided by an effective pharmacy care benefit program. Early findings indicate that at least one half of the Medicare pharmacy benefit costs will be offset by reducing other health care expenditures in the Medicare program. The research will be completed and released later this month.

We have heard proposals discussed today from the Merck/Medco group that would separate a new Medicare pharmacy benefit from the other benefits in the Medicare program. They suggest that we use managed care to administer it.

I think it must be understood that managed care entities have sought to achieve their promise of cost savings largely through restricted community drug store networks and by limiting the type and brand of drugs the patient can receive to established restrictive

drug formularies. This approach simply is not right for Medicare; it's not right for the elderly; and Community Retail Pharmacy will firmly and actively oppose it.

We also want to emphasize that the right of the elderly to freely choose their pharmacy will not be preserved by simply someone with a vested interest promising in their limited choice management program that "any willing provider" will fix the problem or, I should say, loosely using the phrase "free market" in their proposal.

A final word on equal access for drug stores to pharmaceutical manufacturer discounts, sometimes referred to as the discriminatory pricing issue.

The coalition supports proportionate and quantifiable discounts justified by efficiencies and economies returned to the manufacturer. We are not suggesting a single manufacturer price for prescription drugs nor doing away with volume discounts.

It is, however, a fact that large chain drug stores and large volume community pharmacy buying groups made up of small drug stores simply do not get the same discounts from pharmaceutical manufacturers as many of the manufacturers preferred purchasers do, such as HMO's, hospitals, and mail order companies, who often offer less volume to the manufacturer. Community Retail Pharmacy, which purchases 60 percent of all prescription drugs, should have access on proportionally equal terms to the same discounts pegged to volume that are offered to all other purchasers, including those competing directly with us, such as mail order companies.

Locking out by manufacturers of community retail pharmacy, large and small, from equal access to discounts is something that simply must be ended. It will lower overall prescription costs and surely benefit the consumer.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you very much, Mr. Ziegler.

[Testimony resumes on p. 779.]

[The prepared statement of Mr. Ziegler follows:]

## STATEMENT OF RONALD L. ZIEGLER

This written statement is submitted on behalf of the Community Retail Pharmacy Health Care Reform Coalition (the "Coalition"), and supplements the oral testimony delivered by Ronald L. Ziegler, President of the National Association of Chain Drug Stores, on behalf of the Coalition. The Coalition consists of the National Association of Chain Drug Stores ("NACDS") and the National Association of Retail Druggists (NARD). Together, the Coalition represents over 112,000 pharmacists and one million employees serving in more than 60,000 community retail pharmacies. Community retail pharmacies dispense approximately 90 percent of all outpatient prescriptions filled in the United States, accounting for nearly two billion prescriptions annually, valued at approximately \$50 billion.

Prescription drugs and professional pharmacy services rendered by a community retail pharmacist play an essential role in the delivery of preventive health care. The Coalition was formed in February 1993 to support the President's call for universal health care coverage that includes a comprehensive prescription drug benefit and continuing, ready access for all citizens to their local retail pharmacist. The Coalition is proud to endorse the President's health care reform plan.

The Coalition recognizes that the Congress will be examining all aspects of health care reform legislation. As Congress undertakes this important process, the Coalition strongly urges preservation of several essential features of the Administration's health care reform bill, H.R. 3600:

- Universal health care coverage should provide for comprehensive preventive care, including a prescription drug benefit and pharmacy services.



- A prescription drug benefit should be available that permits the elderly to choose their pharmacy, including persons covered by Medicare.
- Individuals should have freedom of choice to fill their prescriptions with professional pharmacists at community retail pharmacies.
- Prescription drug reimbursement formulas should recognize a competitive community retail pharmacy market which contributes to cost-containment.
- Nationwide electronic information systems, which are being developed by the retail pharmacy industry, should be integrated into a uniform claims administration system; electronic information systems also help retail pharmacists provide patient counseling regarding each prescription and refill.
- Today's competitive retail prescription drug market should be preserved and enhanced by ending manufacturers' discriminatory pricing practices which favor isolated segments of the market by cost-shifting to community retail pharmacies' customers.

Our written statement elaborates on each of the above principles.

## **I. A Prescription Drug Benefit Should Be An Essential Element of a Comprehensive Preventive Health Care Package**

Prescription drugs contribute substantially to preventive health care.

Prescription drugs reduce both the severity and frequency of chronic ailments, easing patients' pain, speeding recovery, and forestalling deterioration of patients' conditions. Prescription drugs not only keep us healthy and ameliorate pain, they directly reduce the need to seek further primary care. Making prescription drugs available as part of a comprehensive health care package will be a cost-effective means of containing primary and tertiary health care costs.

Community retail pharmacists serve an essential role in the cost-effective delivery of prescription drugs. Retail pharmacists are the most accessible health care professionals. Pharmacists are available where patients need them -- in over 50,000 local drug stores, in 5,000 supermarkets, and in 4,000 mass merchandising establishments -- and when patients need them, without the need of an appointment, and often being available around the clock. Retail pharmacists do much more than dispense prescriptions. Retail pharmacists provide critical counseling and pharmacy services to millions of customers every day. Pharmacists advise patients on the proper use and dosage of prescriptions, precautions, possible side-effects, and the availability of generics. Pharmacists also give advice on over-the-counter drugs and medical and therapeutic devices and treatments. Pharmacists will soon have electronic access to most consumers' prescription drug records and will be able to more readily identify problems between conflicting medications. Retail pharmacists are thus able to provide continuity of pharmacy care which is so essential to sound and safe drug treatment.

Most Americans often rely on personal advice from their local pharmacist. It is not surprising, but quite revealing, that consumer polling conducted by the Gallup organization, consistently ranks pharmacists as America's most trusted professionals, as was the case in 1993 for the fifth consecutive year.

There will be those who argue that a prescription drug benefit is too expensive and should not be part of a basic benefits health care package. This view would be dangerously short-sighted. The appropriate use of prescription drugs provides tremendous savings to our health care system, by reducing the need for more extensive primary care or hospitalization. Individuals who cannot afford prescription drugs frequently turn up in emergency rooms or doctors' offices for treatment that could have been avoided if they had earlier received drug therapy.

Many prescription drugs actually save more than they cost by preventing more serious and frequent illnesses. Prescription drug therapy has been documented to save the nations' health care system billions of dollars in foregone hospitalization and surgery. NACDS recently commissioned a study being prepared by the respected consulting company Lewin-VHI, which reveals that many prescription drugs reduce direct medical costs and indirect social costs, by, for example, increasing life expectancies and increasing productivity. While it may not be possible to quantify the cost effectiveness of all prescription drugs, the Lewin-VHI study presents a review of some of the most frequently prescribed drug therapies for the Medicare population. Based on its review of the clinical economic literature, the Lewin-VHI study is expected to conclude that widespread availability of prescription drugs would result in direct medical savings and save lives.

## **II. An Outpatient Prescription Drug Benefit Should Be Available Especially for the Elderly under Medicare**

The President's health care reform plan extends a comprehensive prescription drug benefit to persons covered under the Medicare program. Congress should preserve this important aspect of Medicare as a component of universal health coverage.

Outpatient prescription drugs are especially important to the elderly. Unfortunately, today, nearly half of the Medicare population, approximately 16.6 million persons, have no outpatient prescription drug coverage of any kind. A recent Congressional Budget Office ("CBO") report estimated that 56.3 percent of Medicare beneficiaries pay more than 90 percent of their drug costs out-of-pocket. Another study on drug use by the elderly found that between 10 and 21 percent of the surveyed population who reported their health as fair or poor reported taking no prescription drugs. The elderly who lack employer-provided or Medigap prescription drug coverage are often subsisting on modest fixed-incomes, perhaps with only the average \$6,600 per year in Social Security benefits, and can not afford prescribed and indicated prescription drug therapies. It is clear that the elderly who are most vulnerable need health care reform that expands access to affordable prescription drugs.

Data compiled by the National Association of Chain Drug Stores from available published sources confirms that nearly half of the Medicare eligible population has no outpatient prescription drug coverage. Of the approximately 35 million Americans in the Medicare population, four million elderly are also covered by the Medicaid program, which provides outpatient prescription drug coverage. Four million elderly have only Medicare coverage, without any Medigap supplement. These



individuals have no outpatient prescription drug benefit at all. Fourteen million elderly are covered by retiree benefit programs sponsored by employers and other entities. Of these 14 million, 91% have some type of prescription drug coverage. The remaining 13 million elderly have Medigap insurance. However, only 13 percent of persons with Medigap coverage have purchased a Medigap prescription drug benefit. Thus, over 11 million persons who purchase Medigap coverage go without outpatient prescription drug coverage. In sum, 47.3% of the Medicare-eligible population, 16.57 million persons, have no outpatient prescription drug coverage.

Prescription drug coverage for the elderly is especially important because the elderly, who represent only about 12 percent of the population, consume approximately 34 percent of prescription drugs. Beyond sheer numbers, prescription drug use by the elderly requires much closer monitoring by pharmacists than drug use by the remainder of the population. Adverse reactions to drugs increase with age. Dosage levels must be closely monitored and drug therapies should be more closely coordinated with a patient's overall health condition. The fact that the elderly frequently have multiple physicians makes the pharmacist's role more important in ensuring that prescriptions are therapeutically appropriate. The personal counseling services offered by community pharmacists, compared to the impersonal dispensing of prescriptions under rigid formularies by institutional operations, is of special importance to the Medicare population.

There are some critics of the President's plan who argue that our health care system needs only insurance reform. Whatever the merits of this argument for the population at large, it clearly does not hold true for the elderly who must rely on

purchasing Medigap insurance to obtain outpatient prescription drug coverage. The problem with relying on Medigap insurance is simply that it is too expensive for the most vulnerable members of the elderly population.

There are ten standard Medigap plans, but only three cover outpatient prescription drugs. Two of these plans provide basic coverage with a deductible of \$250 and a 50 percent co-pay, up to a coverage maximum of \$1,250 per year. To receive the maximum benefit, a person must pay \$2,750 for drugs, on top of the total plan premium. The third Medigap plan offers coverage with a deductible of \$250 and a 50 percent co-pay, up to a maximum of \$3,000 per year. To receive the maximum benefit under this plan, an enrollee would be required to spend \$6,250 for drugs on top of the premium. Unlike the proposed Medicare benefit which limits a recipient's out-of-pocket expense to \$1,000 annually, the Medigap policies limit coverage to \$1,250 to \$3,000 per year. (See Attachment I.)

It is not surprising that more than half of the non-Medicaid elderly can not afford to pay both the high premiums and high co-payments for Medigap outpatient prescription drug benefits. For a person living on a fixed income of an average Social Security check -- \$550 per month -- the cost of Medigap coverage for outpatient prescription drugs is out of reach.

The President's plan makes outpatient prescription drugs more affordable than Medigap policies. The President's plan calls for a \$250 deductible, with a 20 percent co-pay, up to a maximum annual out-of-pocket cost of \$1,000. Medicare beneficiaries would also pay about small premium for outpatient prescription drug coverage.

It is true that the President's plan makes outpatient prescription drugs more affordable to the elderly by increasing Medicare spending. However, such spending represents cost-effective preventive care that will return dividends in the form of reduced direct and indirect health care costs. The net cost to the federal government will be substantially less than the initial outlays. Moreover, the benefits to society from longer lives, increased productivity, and greater personal dignity for the elderly are substantial, if incalculable.

Lewin-VHI is examining three areas in which the Medicare outpatient prescription drug benefit will produce measurable savings to offset its budgetary cost. First, by lowering the cost to individuals, the President's plan will expand coverage and utilization of drug therapies. Increased utilization of appropriate drug therapies can reduce the severity and frequency of some of the most common conditions afflicting the elderly. Based on comprehensive cost identification studies for just five common conditions -- GI bleed, glaucoma, staph infection, schizophrenia, and ulcers -- Lewin-VHI preliminary estimates that more widespread drug utilization will reduce Medicare spending. This is a conservative estimate, because it assumes no savings from other similar conditions for which comprehensive cost identification studies have not yet been published in the medical literature.

A second net cost savings arises from the President's comprehensive outpatient prescription drug program, through reduced drug-induced disease and drug-related hospital admissions should save the Medicare program billions annually. Third, net cost savings will result from drug utilization review and counseling as envisioned in the President's plan. Moreover, nationwide electronic claim information

systems that link almost every community retail pharmacy are already in place to facilitate patient profiling, drug utilization review, pharmacist counseling, and generic substitution. This effective pharmacy care is estimated to result in significant annual Medicare savings.

The Center for Health Policy Studies also concludes that the direct cost of the Medicare outpatient prescription drug benefit will be offset by cost reductions elsewhere in the health care system, in the form of reduced hospitalizations and less need for physician care.

If the prescription services are uniformly and effectively used nationwide, as could be done under the electronic claims system as envisioned in the President's bill, at least half of the initial outlay costs of a Medicare outpatient prescription drug benefit will be returned in the form of decreased acute medical care costs. In all likelihood, these savings are understated. Moreover, direct budgetary savings do not include the benefits of longer, healthier, more dignified and more productive lives. Thus, the cost of the proposed Medicare outpatient prescription drug benefit is far less than meets the eye and is testament to the effectiveness of preventive health care.

### **III. Individuals Should Enjoy Freedom of Choice and Ready Access to Community Retail Pharmacies**

Community retail pharmacies are found in every locality in America; there are more than 60,000 nationwide. In most areas, the retail pharmacy market is fiercely competitive. With respect to outpatient prescription drugs, retail pharmacies' mark-ups are small and price-gouging is impossible. While there has been increasing public



concern about the rapid increases in the cost of pharmaceutical products, all experts acknowledge that manufacturers' pricing practices, rather than wider retail margins, are responsible for recent years' rapid increases in drug prices.

The President's health care plan focuses much of its reform effort on achieving more efficient health care at the primary care level. Thus, the President's plan, as well as other legislative proposals, encourages the role of primary care physicians as gatekeepers into the delivery system. With respect to pharmacy care, community pharmacists already perform important primary care services. The local retail pharmacist can best manage pharmacy care and ensure effective drug utilization. It would be absolutely counterproductive for a health care reform system to deprive individuals of their relationships with local pharmacists or to drive community retail pharmacies out of business.

Some critics of the President's plan may propose that the Medicare outpatient prescription drug benefit be administered through a managed care plan rather than through the individual's local pharmacy of choice. These critics would claim that managed care administration would save money and be more consistent with the managed competition ideals of various reform proposals. The Coalition strongly urges Congress to reject proposals for a mandatory Medicare managed care prescription drug benefit. In fact, these proposals would substantially reduce competition, diminish the effectiveness of pharmacy care, and undermine the solvency of thousands of retail pharmacies and greatly diminish access to community-based health care providers.

The President wisely concluded not to eliminate the Medicare program and to retain the elderly population's complete freedom of choice in selection of primary care physicians. Such freedom of choice is just as crucial to the elderly in seeking pharmacy care. This group has seventeen prescriptions per year dispensed to them, compared to about seven for the rest of the population. Moreover, 93 cents of every dollar they spend for outpatient prescription drugs is spent on drug therapies for chronic conditions. Personalized pharmacy care and counseling, which that can best be provided by their community retail pharmacists, is especially important for those with chronic, often debilitating, conditions.

A mandatory Medicare managed care prescription drug program would substantially limit the elderly's access to pharmacies of their choice. The elderly might be forced to journey longer distances to impersonal institutional dispensaries or to rely on mail-order facilities to fill prescriptions. The elderly would lose the convenience of going to their nearest or favorite pharmacy. Pharmacy care would lose the personal touch, which means so much to effective drug utilization.

There is no credible evidence that a mandatory managed care pharmacy benefit would substantially reduce costs of providing pharmacy care or maintain the quality of existing pharmacy care services provided by the nation's network of over 60,000 local pharmacies. While some studies show that restrictive formularies may reduce initial prescription drug expenditures, such reductions are generally offset by increased hospitalization and physician care caused by substitutions of drugs in response to the restrictive formularies. That is, cost-oriented formularies and mail-order operations may cut costs on drugs by forcing inadequate drug therapies on patients which causes subsequent increases in primary health care costs.

While the net savings, if any, from mandating a managed care pharmacy benefit are inconclusive at best, the economic effects on the retail pharmacy industry would be devastating. If a substantial number of Medicare patients were required to use only managed care or mail-order pharmacies to fill outpatient prescription drugs, community retail pharmacies would lose a substantial customer base, threatening their financial viability. Retail price and service competition would be substantially reduced for all individuals, whether or not covered by Medicare. Alternative delivery methods, such as mail-order, can not exist without community pharmacies to fill their service inadequacies.

#### **IV. The President's Cost Reimbursement Formulas Will Enhance Retail Competition and Contribute Significantly to Cost Containment**

The President's Medicare outpatient prescription drug benefit contains a reimbursement formula that is equitable for retail pharmacies and conducive to meaningful cost containment. Under the President's reimbursement formula, a retail pharmacy will be entitled to receive the lesser of (i) actual charges, (ii) the 90th percentile of actual local charges for a particular drug, determined during the second previous calculation period, or (iii) 93 percent of the average wholesale price during the current calculation period, plus an administrative allowance of \$5.

The highly competitive retail pharmacy market keeps profit margins relatively low and precludes unjustified price increases. (See Attachment II.) Moreover, under the Administration plan, retail reimbursement would be capped by this "lower of" formulation, thereby insuring justifiable reimbursement to community retail pharmacies.

The proposed Medicare reimbursement formula will produce real cost containment from the inception of the President's plan. It is estimated that retail pharmacies will receive \$400 million less in reimbursements annually as a result of the "lower of" formula for reimbursement. This \$400 million represents real savings for the Medicare system, relative to current retail pricing patterns. Thus, the community retail pharmacy industry is not advocating a new prescription drug benefit without being willing to make contributions to national health care savings. In fact, the Medicare reimbursement program is structured to require contributions from both retail pharmacies and from manufacturers in the form of rebates expected to total \$1.6 billion and from individuals in the form of a small premium, a \$250 deductible, and 20% co-pay, up to a \$1,000 maximum out-of-pocket costs.

The cost-saving contributions by retail pharmacies (through reduced reimbursement) and drug manufacturers (through rebates) are especially equitable when viewed in the context of their relative operating profits. The average operating profit in the community retail pharmacy industry is about 2.2 percent. By contrast, drug manufacturers enjoy operating profits that exceed 16 percent.

Despite its restraining effect on retail prices, the Coalition supports the reimbursement formula, provided that the competitive retail pharmacy market is enhanced by proposed changes in manufacturers' discriminatory pricing practices. However, the Coalition suggests that the reimbursement formula be modified in a technical respect to provide more equitable reimbursement. The Coalition recommends that calculation of the 90th percentile of actual local charges be based on a rolling 30-day price. As currently written, the law would peg reimbursement rates to drug prices



that range from 6 to 18 months old. The excessively long lag in the formula as currently proposed would unfairly reduce pharmacists' reimbursements by whatever amounts manufacturers had raised prices across the board during the that period.

**V. The Retail Pharmacy's Nationwide Electronic Information System Leads the Way for Uniform Claims Administration and Cost-effective Counseling**

The President's health care reform plan is designed to establish uniform national standards for electronic processing of medical information, including claims forms, patients' medical and prescription drug histories, and utilization review information. It is widely believed that simplification of medical and administrative paperwork will contribute greatly to a more efficient and less costly health care system. The Coalition is likewise committed to the establishment of uniform electronic information systems which will standardize claims processing and eliminate unnecessary administrative layers. In fact, the community retail pharmacy industry is now putting in place an open access, nationwide, electronic information system that will permit achievement of the President's desired uniform electronic claims system. Even more importantly, the industry's electronic information system will enable, to the extent permitted by law, almost every community pharmacy to access a patient's prescription drug history and to thereby provide meaningful counseling on proper drug therapy.

The availability of the uniform electronic information system will enable pharmacists to correct prescribing errors and cut down on inconsistencies in prescriptions. One academic study found that pharmacists intervene to correct prescribing errors on 1.9 percent of all new prescriptions with an average savings in foregone hospital and other medical costs of \$123 per intervention. (Rupp, et al, 1992)

Pharmacy care consists of more than prescribing a "correct" medication. High quality pharmacy care requires a professional pharmacist who ensures that a patient does not receive harmful combinations of medications or excessive quantities of medication, and that the patient understands dosage limitations and is aware of potential side-effects. The electronic information system now in place for community retail pharmacies nationwide enables patients to receive the most cost-effective prescription drug treatment.

The Coalition believes that the retail pharmacy industry's pioneering electronic information system can serve as a model for more comprehensive medical information systems that are envisioned in most health care reform proposals.

#### **VI. Health Care Reform Must Prohibit Manufacturers' Discriminatory Pricing Practices**

The President's health care reform plan recognizes that effective competition in the retail pharmacy market requires that all retailers have equal access to manufacturers' pricing terms. Accordingly, H.R. 3600 prohibits manufacturers from engaging in discriminatory pricing practices. Manufacturers must offer substantially the same terms for discounts to each purchaser of covered outpatient drugs. Manufacturers' pricing discounts must be justified by cost savings and be offered to all purchasers that meet such economic justifications. Thus, manufacturers may offer discounts for prompt payment, cash payment, volume purchases, single-site delivery, use of formularies by purchasers or other circumstances that effectively reduce the manufacturer's costs. Any pharmacy that complies with the discount requirements or conditions shall be entitled to equal access to price discounts.

The non-discriminatory pricing provisions in the President's bill are designed to eliminate manufacturers' existing pricing practices which result in substantial, non-justified discounts being offered to limited segments of the pharmacy market, such as individual HMOs, hospitals, or mail-order pharmacies, as a means of securing market share. With discriminatory pricing practices, manufacturers may offer discounts to selective purchasers of as much as 50-90 percent off the price charged to retail community pharmacies. These discounts are not based on any justifiable cost savings to the manufacturer such as volume and are, for the most part, merely marketing schemes. (See Attachment III.)

To provide these arbitrary discounts, manufacturers shift costs to the retail pharmacy sector in the form of higher prices than those that would be charged in the absence of discriminatory pricing. Moreover, there is no evidence that manufacturers' selective discounting results in significantly lower prices to patients. In fact, discriminatory discounts generally benefit the HMO, hospital, or mail-order pharmacy by reducing its costs without a commensurate reduction in charges assessed patients for covered drugs. Thus, third-party payors and Medicare programs generally do not receive the benefit of these price discounts.

The Coalition wants to make clear that the proposed "equal access to discounts" provisions do not prohibit economically justified volume discounts. However, under current practices, discounts offered large HMOs are not made available to the largest chain drug stores or retail buying groups. It is this disparity in pricing practices, which is not cost-justified, that is targeted by the President's bill.

If discriminatory pricing practices are eliminated, retail pharmacies can compete vigorously in the retail marketplace for outpatient prescription drugs. If Congress does not act decisively to end these practices, retail pharmacies will be increasingly disadvantaged and their continued solvency will be threatened, consumer access reduced, and the fierce competition community retail pharmacies bring to the marketplace would be removed.

## VII. Conclusion

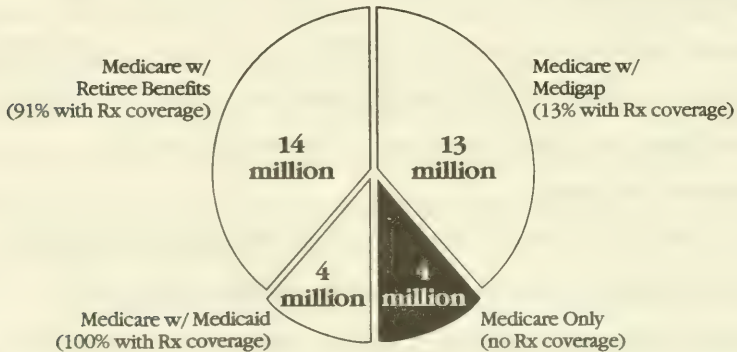
The Community Retail Pharmacy Coalition believes that health care reform legislation should provide universal coverage with a meaningful outpatient prescription drug benefit for all Americans, including Medicare beneficiaries. An outpatient prescription drug benefit saves substantial direct and indirect medical costs, while entitling all Americans to the benefits of cost-effective preventive care. As with all other basic health care benefits, individuals should be guaranteed meaningful access to retain existing provider relationships, including their local pharmacy with equitable reimbursement for providers.

Health care reform will maintain our nation's highest quality of pharmacy care only if the highly competitive and professionally valuable community retail pharmacist is preserved and enhanced. Proposals to restrict Medicare beneficiaries to single managed care vendors of pharmacy services or to mail-order prescription drug operations will reduce competition and lessen the personal involvement of pharmacists in providing valuable pharmacy services. The elimination of manufacturers' discriminatory pricing and the establishment of a national electronic information system will enhance competition that will bring market-driven savings to the health care system. The Coalition respectfully recommends that Congress embrace these principles of the President's health care reform plan and enact a comprehensive outpatient prescription drug benefit which can be cost-effectively delivered by the nation's 60,000 community retail pharmacies.



Health-Care and Pharmaceutical Insurance for the Elderly<sup>1</sup> (1992)

Type of Coverage <i>Total persons with coverage</i>	% of Covered with Rx Benefit	# (in millions) with Rx Benefit	# without Rx benefit
Medicare w/Medicaid <i>4 million beneficiaries</i>	100%	4 million	0
Medicare ONLY <i>4 million beneficiaries</i>	0	0	4 million
Medicare w/Medigap <i>13 million beneficiaries</i>	13%	1.69 million	11.31 million
Medicare w/Retiree <i>14 million beneficiaries</i>	91%	12.74 million	1.26 million
<b>TOTAL</b> <i>35 million beneficiaries</i>		<b>18.43 million</b>	<b>16.57 million</b>
<b>% OF TOTAL MEDICARE POPULATION</b>		<b>52.7%</b>	<b>47.3%</b>

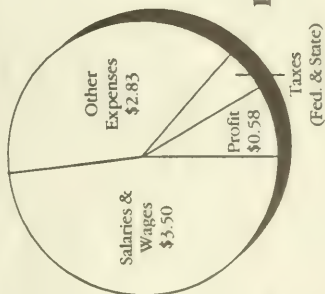
<sup>1</sup>Sixty-five years old or older.

Source: AARP, HCFA, and Bernstein estimates.

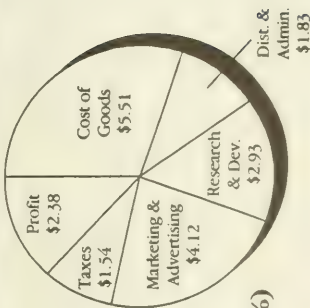
# Components of Retail Prescription Price in the United States

1993 Rx = \$26.93

**Retail Pharmacy \$7.27 (27%)**



**Drug Manufacturer \$18.32 (68%)**



**Drug Wholesaler \$1.34 (5%)**



**Profit as a Percent of Average Prescription Price**

Drug Manufacturer	8.8%
Retail Pharmacy	2.2%
Drug Wholesaler	1.7%

Source: PRIME Institute, February 1994

## SELECTED PRICE COMPARISONS

Discounted price  
to non-community  
pharmacies such as  
HMOs, hospitals, clinics,  
nursing homes & mail-  
order businesses

Premium  
Paid By  
Community  
Pharmacies

Manufacturer	Product	Quantity	Price to Community Pharmacies	Premium Paid By Community Pharmacies
Ciba-Geigy	Transderm- Nitro (Cardiac)	30 Patches	\$ 8.40	\$ 39.89 375%
Glaxo	Ventolin 4mg (Respiratory)	500 Tablets	63.84	183.71 188%
Searle	Calan 40mg (Cardiac)	100 Tablets	3.90	22.91 487%
Wyeth	Inderal 60mg (Cardiac)	100 Tablets	4.12	48.31 1073%
Smithkline	Eskalith CR 450mg (Lithium)	100 Capsules	17.18	23.02 34%
Schering- Plough	K-Dur 20meq. (Potassium)	100 Capsules	2.03	27.31 1245%

Mr. WAXMAN. I want to commend this panel on its testimony.

There are two proposals that have been circulated that would decentralize the administration of the Medicare drug benefit. Under one proposal, the benefit would be administered by pharmaceutical benefit managers such as Medco, for example. Under another proposal, the benefit would be administered by the managed care formularies. I would like to ask each of you to indicate whether you are familiar with these proposals and, if so, to comment on them.

Mr. Carver.

Mr. CARVER. Mr. Chairman, I am unable to speak for our coalition with regard to evaluating either of those proposals.

With respect to Kaiser Permanente, it certainly is our view that there should be a Medicare prescription drug benefit and that prescription drug benefit should be offered as a stand-alone benefit.

Mr. WAXMAN. Mr. Marshall.

Mr. MARSHALL. Our association has certainly supported the Medicare drug benefit all the way, actually for all citizens as well.

In terms of the two proposals out there, if pharmacy benefit managers take over the Medicare component or all of the component on a regional basis, we would certainly hope and ask you to help us assure that their primary way of dealing with pharmacy providers is not simply, as Mr. Ziegler pointed out, to continually ratchet down reimbursement to below cost levels. Most pharmacies are providing substantial amounts of services at below cost levels right now and many have gone out of business for that.

Mr. WAXMAN. But do you think there ought to be a formulary, or do you think there ought to be some group to manage the pharmaceutical benefit?

Mr. MARSHALL. There can be both. We certainly support the use of formularies. In fact, we've introduced legislation this year in the California legislature to give outpatient pharmacists more flexibility and more leeway in working with formularies so that each use of a formulary doesn't necessarily cost a telephone call trying to hunt down the prescriber. But with protocols, formularies could be worked out with the pharmacist and the prescriber ahead of time.

One of the things that Merck/Medco has done, or has talked about at least, is something called the coordinated care network whereby they will pay pharmacists for managing generic utilization and managing formulary utilization and then hopefully managing drug therapy in general. We support that. We just haven't really seen it come out yet.

Mr. WAXMAN. Mr. Ziegler.

Mr. ZIEGLER. Mr. Chairman, as I mentioned in my testimony, we feel that Medicare prescription benefit should remain where it is.

I should say that what I heard today in the testimony seemed like a cost containment program or an entitlement for the Merck/Medco group. We had their proposal scored by economists who are respected in the health field, and if you take a good look at their proposal, what it does, quite frankly, is shift the scored costs that they now are contributing under the Medicare program to us, to community pharmacy. It reduces their contribution to the Medicare program savings by \$1.4 billion and increases community pharmacy contribution by 300 percent. So it reduces their contribution by 52 percent and increases ours by 300 percent.



In terms of your question relevant to formularies, formularies, when you are dealing with the Medicare population, have to be looked at very carefully. The interaction between the doctor and pharmacist when you are dealing with people over 65 in terms of the reaction of the various drugs or substitution of drugs can have a profoundly negative impact on overall health care costs.

Mr. WAXMAN. I'm going to have to stop you there. I appreciate that answer.

Mr. Carver, I'm interested in your reaction to Mr. Marshall's testimony in support of any willing pharmacy provider requirement. In particular, do you agree with the contention that the use of limited or exclusive pharmacy networks by managed care plans like Kaiser "create confusion and inconvenience for patients and animosity among pharmacies, physicians and patients alike"?

Mr. CARVER. Mr. Chairman, with regard to responding on behalf of Kaiser Permanente, we own and operate and deliver pharmaceutical services within our program, as I believe you know. We are not in the position of contracting with either chain or community drug stores for the delivery of health care or pharmacy services to our members of Kaiser Permanente.

With regard to whether or not there should be open access, that is beyond the scope of what I am prepared to respond to. I would really like to limit my responses to the rebate and the discount issues.

Mr. WAXMAN. Mr. Marshall, you testified in support of a requirement that enrollees in managed care plans be able to use any willing pharmacy provider. Under the President's plan, as I understand it, health plans that offer their enrollees the lower cost sharing schedule must also offer them the opportunity to obtain coverage for out of network items and services, including prescription drugs furnished by providers that are not members of the plan's network.

Isn't this so-called point of service provision the same as your "any willing pharmacy provider" proposal, and if not, what are the differences and what changes do you believe need to be made in the President's plan?

Mr. MARSHALL. I think as long as pharmacies have the ability to participate using the same processing and drug utilization review systems as any other providers and the patients have those choices and are not economically penalized for making those choices, and as long as those pharmacies are willing to meet the contractual and the service provisions, I think they ought to be included.

Mr. WAXMAN. Mr. Carver, I don't know if you are prepared to do it now, but I think it would only be fair since Mr. Bliley ran a video that involved Kaiser in Sacramento to respond to that video. You can do it now or put something in the record, however you see fit. Do you want to comment on it?

Mr. CARVER. I would be happy to comment now, Mr. Chairman. Obviously this was a controversial decision and a very emotional issue.

First, I would like to explain the decision of the Permanente Medical Group in Northern California. I assure you that that decision was not based upon cost at all. Our neurologists have reviewed very thoroughly the medical and scientific literature regarding the

product Cognex. While there is agreement that there may be a modest improvement for a minority of patients who are suffering from Alzheimer's and in spite of the fact that I believe that we all wished this were a very effective and breakthrough drug, it's not.

We have very serious concerns about the high incidence of toxicities for patients, a 40 percent incidence of liver toxicity, and in some of the studies almost 60 percent of the patients have been discontinued on that particular product.

The neurologist specialists in the Permanente Medical Group of Northern California came to the conclusion that generally we felt concerned about general use of that product in our program and for that reason it was not added to the formulary. That is not to say, however, that Cognex is not used or will not be used for a limited number of patients where the drug is felt to be very appropriate and where we can do the very thorough monitoring of those patients that is necessary. As a matter of fact, the drug is being used in a small number of patients within Kaiser Permanente in the Northern California region.

As I mentioned, it's an emotional issue. Perhaps it grabs media attention, but we believe that our neurologists, the specialists most likely to be using this product in Northern California, have come to a very thoughtful decision regarding its use, and a very appropriate decision.

Mr. WAXMAN. Thank you very much.

Mr. Greenwood.

Mr. GREENWOOD. Thank you, Mr. Chairman.

I would like to address a question to Mr. Ziegler regarding discounts on pharmaceuticals based on volume. How does that work? An HMO is able to make an agreement with a manufacturer for the exclusive use of a particular product. A chain drug store, on the other hand, must service each and every customer based on what prescription he or she has or what particular choice that they would like to make. This is a problem for the chain drug stores, as I understand it. What does the Clinton proposal do to correct that, and do you think that is the right fix?

Mr. ZIEGLER. We feel the Clinton proposal would help correct the situation by providing more competition within the marketplace. The Clinton proposal, as we see it, enhances competition.

What has happened now is brokers have cropped up in the marketplace. They are clustering patient lives. Manufacturers want to get on the formulary created by the HMO or created by the pharmacy benefit management organization. They negotiate simply the lowest price for the formulary. They bring it out into the community pharmacy setting where they know they have to use our resources to accomplish this straight price cutting effort, and it harms us in doing our job in overall counseling and pharmaceutical care, which in fact is the ultimate method for overall health care cost savings.

It is a broker-driven market which you are referring to now, and we see moving the relationship closer to the doctor and the pharmacist at the local market and the local area will benefit everyone and cut costs, not simply price cutting by clustering of patient lives.



Mr. GREENWOOD. Is there something in current law that prevents a pharmacy from making an agreement with a drug manufacturer? In exchange for discounts in price, could a pharmacist promise that each time someone comes in with a prescription for a particular ailment, although it may be a different brand, that he/she would call the individual's physician and get permission to substitute the discounted drug? Does that violate current law?

Mr. ZIEGLER. No. Pharmacists interact with physicians on a daily basis. That's part of drug utilization review.

Mr. GREENWOOD. I understand that. My question is, why can't the chain drug stores obtain the same kind of discounts from the manufacturers that the HMO's do? What the HMO's do is they exchange for a low price a guarantee—

Mr. ZIEGLER. I understand, Congressman. You are talking about market movement discounts. The reality is that community pharmacy large and small, chains, independent, are not given equal access to discounts. They are not given equal access to discounts by the manufacturers.

We advocate, as I said in my testimony, that all pharmacy, all those involved in the purchase of prescription drugs have equal access to the same discounts based on volume. If a manufacturer or a group of payors in a local market want to use a formulary and a manufacturer wants to give a discount to work on the movement of a product based on increased volume and the drug store decides to do that, he should be given the right to do that, large and small. Right now we are locked out of those opportunities and it having a profound negative impact on community pharmacy in America.

Mr. GREENWOOD. I yield back the balance of my time.

Mr. MARSHALL. Mr. Greenwood, if I might respond to that for just a second.

Mr. GREENWOOD. Please do.

Mr. MARSHALL. The California Pharmacists Association has a pharmacy benefits manager as a wholly owned for-profit subsidiary. It's called Pharmaceutical Care Network. We went to a lot of work over the last couple of years to prepare just such a formulary based not really on costs at all, but on the most appropriate therapies in each individual therapeutic area.

At the time we developed the formulary we wrote to pharmaceutical manufacturers, saying we are willing to do exactly that, to contact the physician and say under this circumstance this prescription drug is probably more appropriate therapeutically than the other. We sought rebate contracts on the basis of that formulary and for the most part our letters were not even answered.

I suppose that is mostly because we don't have a proven track record in that area, in the area of outpatient community pharmacy. If you look at Kaiser, if you look at a lot of other closed HMO's, they certainly do have that track record.

Mr. GREENWOOD. Thank you.

Mr. WAXMAN. Thank you, Mr. Greenwood.

Gentlemen, thank you very much for your testimony. We look forward to working with you on this legislation.

We are being summoned to the House floor for a vote. So we are going to take a brief recess only so long as it will take to vote and come back and then we will hear from our last panel.

[Brief recess.]

Mr. WAXMAN. We are pleased to welcome for our last panel Henry Grabowski, Professor of Economics at Duke University, David Green, Director of Health and Welfare Unit, Institute of Economic Affairs, John Lott, Assistant Professor, Wharton School of Business, James P. Love, Director, Taxpayer Assets Project, and Stephen Schondelmeyer, Professor and Director, PRIME Institute.

We want to welcome you to our hearing today. Your statements will be in the record in full. What we would like to ask each of you to do is to limit the oral presentation to 5 minutes.

Dr. Grabowski.

**STATEMENTS OF HENRY G. GRABOWSKI, PROFESSOR OF ECONOMICS, DUKE UNIVERSITY; DAVID G. GREEN, DIRECTOR, HEALTH AND WELFARE UNIT, INSTITUTE OF ECONOMIC AFFAIRS, LONDON, ENGLAND; JOHN R. LOTT, JR., ASSISTANT PROFESSOR, BUSINESS, UNIVERSITY OF PENNSYLVANIA; JAMES LOVE, DIRECTOR, TAXPAYER ASSETS PROJECT, CENTER FOR STUDY OF RESPONSIVE LAW; AND STEPHEN W. SCHONDELMAYER, DIRECTOR, PRIME INSTITUTE**

Mr. GRABOWSKI. Thank you, Mr. Chairman. The Clinton administration's health care reform plan imposes a system of incipient price controls on pharmaceuticals. The most stringent of these controls are targeted towards new drugs, especially major therapeutic advances. These include the Advisory Council on Breakthrough Drugs, the global budget constraints, and the extra Medicare rebates for new drugs.

Under the last provision, the Secretary of HHS could negotiate an extra rebate for all new drugs marketed at a lower price in 21 reference countries and on new drugs whose prices are determined to be excessive. Where HHS and the manufacturer cannot agree on a negotiated rebate, a new drug can be excluded from Medicare coverage.

Referencing U.S. new drug prices to foreign ones in the Medicare program will import the outcomes of foreign regulatory schemes with their diverse objectives into this country. It will almost certainly lead to unintended and undesirable market responses.

For example, U.S. and foreign multinational firms will have incentives to delay the introduction of products into regulated markets with lower expected prices than the United States. The resulting distortions in the international diffusion of new pharmaceuticals will neither benefit United States or foreign patients. The end result will be reduced resources and incentives for new drug innovation.

The Secretary of HHS also can utilize a public utility type cost analysis in determining whether new drug prices are excessive. The Secretary can be expected to invoke this criteria for any new drug that significantly increases the Medicare drug budget no matter how cost-beneficial the drug is to patients. In effect, the most innovative and commercially important new drugs will be susceptible to public utility type price controls.

The incentives for drug research would suffer enormously under this proposed regime of price controls. In this regard, my work on the pharmaceutical industry shows that the distribution of returns



in pharmaceuticals is highly skewed. A large percentage of new drugs tested in man never reach the marketplace. Only about a third of new drug introductions earn premium returns while the majority do not cover average R&D costs.

Given these facts, how many firms will be inclined to pursue lengthy and risky R&D projects if the rewards for major successes are likely to be highly constrained by price controls? John Vernon and I have recently modeled the effects of subjecting the returns on the top decile of new products to a public utility type cost standard. We found a precipitous drop in overall expected returns from new drug introductions. Under these circumstances, the high rate of technological progress that has been characteristic of this industry would not be sustainable.

The introduction of price controls will also have adverse consequences for new drug innovations emanating from foreign firms. The research-oriented pharmaceutical industry is a global industry, and the United States is the world's largest and most important market. The U.S. pharmaceutical industry, however, will be the most adversely affected because it has been the principal source of major therapeutic advances and it also has the highest market shares in this country.

Increasing insurance coverage for outpatient prescription drugs is a worthy objective. While prescription drugs provide the most cost-effective approach to treating many diseases, they are currently the least insured element of basic health care in the United States. However, universal coverage for prescription drugs does not require price controls and global budget constraints. Evolving drug management plans and managed care systems offer a better way for containing pharmaceutical costs. While these organizations have become tough bargainers with pharmaceutical firms over drug prices and quality, they have not curtailed innovation incentives. A pluralistic market-oriented system will continue to reward drug products that offer value to medical patients. One cannot place the same trust in a government system of price controls and global budget constraints.

Mr. WAXMAN. Thank you very much, Dr. Grabowski.

[The prepared statement of Mr. Grabowski follows:]

## Statement

Henry G. Grabowski, Ph.D.

Duke University

House of Representatives, Committee on Energy and Commerce  
Subcommittee of Health and the Environment

February 8, 1994

The Clinton Administration's health care reform plan imposes a system of incipient price controls on pharmaceuticals. The most stringent of these controls are targeted toward new drugs, especially major therapeutic advances. Under the plan, an Advisory Council on Breakthrough Drugs would evaluate the reasonableness of prices for all significant new drug therapies. Furthermore, global budget constraints would be expected to impact disproportionately on new medical technologies, including innovative pharmaceuticals.

All Medicare drug reimbursements would be subject to rebates of at least 17 percent. However, the Secretary of HHS could "negotiate" an extra rebate for all new drugs marketed at a lower price in 21 reference countries and new drugs whose prices are determined to be "excessive." Where HHS and the manufacturer cannot agree on a negotiated rebate, a new drug can be excluded from Medicare coverage. Under the proposed legislation, a new drug is defined as any drug first marketed in the United States after June 30, 1993.

Referencing U.S. new drug prices to foreign ones in the Medicare Program will import the outcomes of foreign regulatory schemes with diverse objectives into this country. All twenty-one of the cited countries regulate drug prices in one way or another.

Most of these countries have significantly lower standards of living than the United States. Few have research intensive pharmaceutical and biotechnology industries of any consequence.

Utilization of a foreign reference pricing scheme will almost certainly lead to unintended and undesirable market responses. For example, U.S. and foreign multinational firms will have incentives to delay the introductions of products into markets with lower expected prices than the United States. The resulting distortions in the international diffusion of new pharmaceuticals will neither benefit U.S. or foreign patients. The end result will be reduced resources and incentives for new drug innovation.

The Secretary of HHS also can utilize a public utility-type cost analysis in determining whether new drug prices are excessive (either costs supplied by manufacturers or estimated by HHS). The Secretary can be expected to invoke this criteria for any new drug that significantly increases the Medicare drug budget, no matter how cost beneficial the drug is to patients (1). In effect, the most innovative and commercially important new drugs will be susceptible to public utility-type price controls. It should be kept in mind that Medicare will be a larger purchaser of drugs than almost all other countries with single payor systems. In addition, the Advisory Council on Breakthrough Drugs will be located within HHS and will be utilizing the same criteria to evaluate drug prices both within and outside the Medicare program.

The incentives for drug research would suffer enormously under this proposed regime of price controls. One cannot think of

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another industry where there is more potential to do harm to innovation incentives. In this regard, my work on the pharmaceutical industry shows that the distribution of returns in pharmaceuticals is highly skewed (2) (3). A large percentage of new drugs tested in man never reach the marketplace. Only about a third of new drug introductions earn premium returns while the majority do not cover average R&D costs. If profits on these major commercial successes are held to costs plus a "fair" rate of return, expected aggregate returns will not be sufficient to bring forth the desirable level and type of R&D expenditures.

Put another way, how many firms will be inclined to pursue lengthy and risky R&D projects if the rewards for major successes are likely to be highly constrained by price controls? John Vernon and I have recently modeled the effects of subjecting the returns on the top decile of new drug products to a public utility type cost standard (4). We found a precipitous drop in overall expected returns from new drug introductions. Under these circumstances, the high rate of technological progress that has been characteristic of this industry would not be sustainable.

The introduction of price controls here will not only affect U.S. firms, but will also have adverse consequences for new drug innovation emanating from foreign firms. This is because the research-oriented pharmaceutical industry is a global industry, and the United States is the world's largest and most important market. The U.S. pharmaceutical industry, however, will be most adversely affected because it has been the principal source of major



therapeutic advances, and it also has the highest market shares in this country (5).

The proposed price controls on new pharmaceuticals are likely to have especially devastating effects on the dedicated biotechnology sector. Currently this group of firms is in the early stages of its evolution with R&D activities spread over hundreds of relatively small research-oriented firms. While the majority of these firms may be unsuccessful, the prospect of "winning the R&D lottery" has been a powerful economic force attracting venture capital and external investment funds. Currently all but the very largest biotech firms operate with "burn" rates of only a few years in terms of available cash for R&D. Few are likely to survive a system of controls targeted to breakthrough products.

Increasing insurance coverage for outpatient prescription drugs is a worthy objective. While prescription drugs provide the most cost-effective approach to treating many diseases, they are currently the least insured element of basic health care in the United States. However, universal insurance coverage for prescription drugs does not require price controls and global budget constraints. Evolving drug management plans and managed care systems offer a better way for containing pharmaceutical costs. While these organizations have become tough bargainers with pharmaceutical firms over drug prices and quality, they have not curtailed innovation incentives. A pluralistic market-oriented system will continue to reward innovative products that offer value

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to medical patients. One cannot place the same trust in a government system of price controls and global budget constraints.

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Mr. WAXMAN. Mr. Green.

### STATEMENT OF DAVID G. GREEN

Mr. GREEN. Thank you, Mr. Chairman. The main lesson that I want to highlight in bringing evidence about the British system is how not to organize a health care system. Let me present my arguments from two standpoints. One is from the point of view of the public policy maker and the other from the patient standpoint.

First, briefly, from the standpoint of the public policy maker. Promising free care for everybody may seem at first sight to be a pretty good way of winning votes. The British politicians have already made that mistake and it hasn't worked out that way. Once people discover that treatments are withheld, treatments are being delayed, then they demand more public spending; they blame the politicians; and what seemed like a certain vote winning strategy has in fact become a constant source of unremitting political dissatisfaction.

Now some remarks about the British system from the patient standpoint. It is important to remember that there has been a dramatic change in the attitude of patients in the last 20 to 30 years and that price control really belongs to the age of paternalistic medicine.

When the British National Health Service was founded in 1984, doctors were remote paternalists who issued doctor's orders. A measure of this change was symbolized just a few weeks ago when a television program was being made and a British doctor told the interviewer how some of his female patients when he was a younger man, just after the war, used to curtsy upon entering the surgery. He rather regretted the passing of this habit. But the fact is that no one these days, hardly anyone, I should say, regards doctors as authority figures. They are looked upon more as learned advisers whose task is to spell out the options, to explain the risks, to explain the benefits, to explain the costs of the alternative therapies available.

Let me just give one example of patients with high blood pressure. It would be very cheap to take diuretics, for example. That is one possibility. There are certain risks associated with it. It's not so effective. It's a little bit more effective, a little bit more chance of success, but it costs more if you take a beta blocker, but they have some side effects. Or it's very expensive to go for the newer, safer, more effective remedy, for instance, the ACE inhibitor.

How does one balance risks, benefits and costs? Someone has got to do it. The only question is, who does it, whether it is to be enforced by the political authorities and the medical authorities or whether it's to be shared between the patient and the doctor? The only real question is, who decides?

The lesson of the British experience is that when the government starts paying the bill, then it decides, and rationing has been the inevitable outcome.

One brief example. I've given a few in the written testimony. In a study of patients undergoing anticancer therapy in five European countries, the U.K. doctors prescribed a drug known as ondansetron to 50 percent fewer patients than the other four nations. Why is this important? Patients undergoing cancer chemo-

therapy often experience very severe vomiting, in some cases so severe that they dislocate their jaw. But the guidelines to the consultant oncologist at London's Royal Marsden Hospital, which is a major treatment center for cancer patients, say this: "Ondansetron is undoubtedly an effective antiemetic and has the advantage of being virtually devoid of side-effects. However, because of the significantly higher cost, we feel its use should be restricted."

I only discovered this morning in looking at Dr. Sanders' testimony how this contrasts sharper with American attitudes, because he happens to quote an example relating to the same drug when he quotes a doctor in Michigan. This doctor said it is not even ethical to withhold it. That's the difference between a rationing system on British lines and the value system that results from the free American system.

Finally, let me say a word about the GAO report. And I'm going to take a bit of a risk now. Well, I see there is no chairman, so that is rather fortunate, because I'm going to contradict what the chairman said about the GAO report. Or perhaps I should say I am going to respectfully offer an alternative interpretation.

In a statement that was issued at the time of the GAO report, the one comparing U.K. and U.S. prices, Mr. Waxman said that the United Kingdom has found a way to have it both ways, that is, both low prices and drug research. Allow me to submit an alternative interpretation of the evidence.

It's important to remember how small the U.K. market is, only 4 percent of the world market. Top British companies sell only 15 percent of their output in the United Kingdom and half of their output in America. So the successful British companies are financing their research and development with revenues from their sales in America. Does this mean that American consumers are subsidizing successful British companies?

You've got to remember that the successful big British firms—let's take the three biggest, Glaxo, Burroughs-Wellcome, and Smith, Kline, Beech—are really Anglo-American companies that have rather more employees in America than Britain. My estimate is they have 34,000 employees here and 33,000 in Britain. This means that America is not subsidizing overseas research and development but reaping the just reward of its support for innovation and creativity, of the success of the British companies, not therefore because of the peculiarities of British price regulation, which the chairman argued, but the result of America's commitment to liberty to the market system.

Last, if there is any doubt that America's commitment to market competition is a great draw for industry, consider one further example from Germany. Thurringer (phonetic) Manheim, the German company, is now moving its headquarters from Germany to Connecticut, U.S.A., bringing 1,500 jobs with it, because of the stringency of German price controls which have cut spending there by about 8 percent this year.

My main message is this, that if you are thinking of copying the British system, please don't. If you do, you will live to regret it.

Mr. WAXMAN. Thank you, Mr. Green.

[Testimony resumes on p. 815.]

[The prepared statement of Mr. Green follows:]



## Testimony of Dr David G. Green

### The Current System

In the United Kingdom there are about 34,000 general medical practitioners providing medical care under the NHS. In England the general medical service is administered by 90 Family Health Services Authorities (FHSAs) with eight more in Wales. The FHSAs also manage the pharmaceutical, general dental, and ophthalmic services. In Scotland the 15 Health Boards manage both the hospitals and family health services, as do the four Health and Social Service Boards in Northern Ireland. Since April 1991, FHSAs in England have been accountable to the fourteen Regional Health Authorities (RHAs).

### *The Prescription Charge*

When the NHS was established in 1948 all medicines were supplied free if prescribed by a doctor, but it was quickly recognised that this arrangement was unsustainable in the long run and as early as 1949 legislation was enacted permitting a charge of 1s (5p). Even Aneurin Bevan, the minister of health from 1945 to 1951, expressed alarm at the cost of the drugs bill: 'I shudder to think of the ceaseless cascade of medicine which is pouring down British throats at the present time', he said. The charge was implemented in 1952 and has been increased over the years to £4.25 in 1993.

Initially the charge of 1s (5p) was introduced for each prescription form regardless of the number of items on it but in 1956 the charge was levied on every item. Then, in 1961 it was increased to 2s (10p), but the charge was imposed on each prescription form, not on every item. In 1965 it was abolished by the new Labour Government. By 1968 the number of prescription items dispensed had increased to over 300 million per year, having been stable at around 240 million per year since 1952.

By 1968 the Wilson Government found itself in financial trouble and had to reimpose the charge at the higher rate of 2s 6d (12½p) per item. The reimposition of the charge led to a prolonged row, reported in Crossman's diaries, and as a *quid pro quo* the charge was not imposed on everyone as had been the previous practice. All children, retired people, expectant and nursing mothers and the chronic sick were exempted. Also in 1968, the pre-payment certificate, or 'season ticket', was introduced which allowed people to pay a fixed amount in advance entitling them to free medicines for up to twelve months. The immediate result of re-imposing the charge was that the volume of prescriptions stabilised.

Since 1968 the system has remained largely the same, though the prescription charge has increased substantially and the number of exemptions has grown. In 1993 the prescription charge stands at £4.25 for every item. A pre-payment certificate lasting four months can be purchased for £22.00 and for twelve months at a cost of £60.60. The pre-payment certificates are obtained by filling in a form which can be collected from chemists, doctors and from the FHSAs. By pre-paying, anyone eligible to pay the prescription charge can ensure that he or

she pays no more than £60.60 in a year, an amount lower than the cost of the TV licence, currently £80.

The prescription charge has risen much faster than the rate of inflation since 1968 and since 1979 the charge has risen by over three times the rate of general inflation, as Table 1, taken from the Office of Health Economics' *Compendium of Health Statistics 1992* shows. The exemptions are shown in Figure 1. They are generous compared with exemptions in other European countries, as Figure 2 shows.

The British exemptions are difficult to justify. All children are exempt, regardless of their parents' income; all the elderly, regardless of income; and oral contraceptives are free for everyone regardless of wealth.

In the UK, exempt patients are not required to pay for any medicines at all, whereas most other countries only exempt patients from co-payment for treatments related to the specified disease. Italy, for instance, has a list of 43 serious diseases for which 100 per cent reimbursement is available and France has a list of 30 (although there is provision for other chronic conditions to be exempted and in such cases all drugs are free). In those countries, therefore, diabetics are typically not required to pay for insulin and oral hypoglycaemics, but must pay for any other drugs, and epileptics need not pay for anti-convulsants but must pay for other medicines.

Moreover, equally chronic conditions requiring continuous drug therapy are not exempt in the UK. Conditions with a strong case for exemption include mental illness, Parkinson's disease, rheumatoid arthritis, cystic fibrosis, pernicious anaemia, asthma and Wilson's disease.

Total revenue raised by the prescription charge was £250m in 1990, or 8 per cent of the total cost of drugs. This is low compared with other European countries as Table 2 shows. In 1990, 82 per cent of UK prescription items were exempt, compared with 2 per cent in Belgium and Switzerland. Spain was closest with 60 per cent.

### *The Dispensers*

GPs use a standard prescription form which is taken by the patient to the chemist. Chemists hold stock which they purchase from manufacturers or wholesalers. They pay their suppliers on credit terms and claim reimbursement from the local FHSA each month. At the end of each month the chemist sends his prescription forms to the Prescription Pricing Authority (PPA), which calculates the amount due to the chemist and notifies the FHSA how much to pay. The chemist's remuneration is based on the 'basic price' of the drug according to a list maintained by the Department of Health, to which is added an on-cost allowance to cover overheads and profit (5 per cent of the total of basic prices), the dispensing fee and the allowance for containers and measuring devices. Finally the PPA deducts an amount to allow for the discounts obtained by chemists in their dealings with manufacturers and wholesalers.

About 94 per cent of prescriptions are dispensed by the chemist and appliance contractors of the FHSAs, but a growing proportion of the total is dispensed by doctors in rural areas where patients have serious difficulty in obtaining medicines because there is no local pharmacist. In the United Kingdom in 1991, there were some 4,289 doctors, 12 per cent of the total, providing dispensing services for around 8 million people.

Chemists must register in accordance with the 1968 Medicines Act. Registration is administered by the Royal Pharmaceutical Society of Great Britain which has a statutory duty to register pharmaceutical chemists who have obtained its diploma. Once registered it is open to a FHSA to award a contract which, *inter alia*, stipulates opening hours and lays down participation in the rota scheme for out-of-hours opening. In 1991 there were 12,287 registered chemist and appliance contractors, 8 per cent up on 1980. Currently FHSAs are reluctant to issue new contracts.

The hospital system is separate. The hospital pharmaceutical service employs salaried pharmacists and technicians to prepare and dispense medicines for hospital in-patients and out-patients.

### ***The Doctors***

General medical practitioners enjoy clinical freedom. Total spending on family health services is not cash limited, unlike the hospital and community health services. The total cost of medicines is subject to a 'firm' budget allocation each year, but the total is not treated as a cash limit, except for GP fundholders.

Five main measures influence GPs prescribing. Some are designed to inform and others to control.

**Information:** GPs are regularly supplied with two kinds of information. The Medicines Resource Centre supplies them with information about therapeutic alternatives to keep them up to date and fully aware of clinical options. They also receive the *Prescriber's Journal*, the *Drug and Therapeutics Bulletin* and the *British National Formulary*.

Secondly, the Prescription Pricing Authority supplies GPs with information to ensure they are aware of the cost of their decisions compared with the average for the locality and the country. Since August 1988, the prescribing patterns and costs of every GP have been monitored by an information system known as PACT (Prescription Analysis and Cost Tables). PACT reports compare practice prescribing with that of the local FHSA and England and Wales as a whole. If the prescribing costs in a practice exceed the FHSA average by 25 per cent or more, or by 75 per cent in any of six major therapeutic groups, then more detailed information is produced to enable GPs to carry out an audit of their prescribing. FHSAs as well as RHAs may also opt to receive more detailed information from the Prescription Pricing Authority.

**Generic Names:** Doctors are encouraged to prescribe generically, and in medical school they are trained to know the generic names of drugs and to use them rather than brand names.

In November 1993, Dr Mawhinney, Minister for Health, announced that between 1982 and 1992 generic prescribing had doubled to 43% of prescriptions. (Hansard, 5 November 1993)

The active ingredient of a medicine may have one of three names. It will have a systematic chemical name, describing its chemical make-up which is mainly used by scientists. It will also have an International Non-Proprietary Name (INN) or British Approved Name (BAN), both of which are also called the generic name. This approved or generic name refers to the active ingredient, not to every substance of which a tablet, capsule or ointment is comprised, and all medicines consist of substances other than the active ingredient. Finally, a drug may have a brand name, which describes the particular formulation of active ingredient and other substances. Because the brand name describes the total formulation and not simply the active ingredient, it is, therefore, more specific than the generic name. *Aspro* is, for instance, a brand name for aspirin, *Panadol* for paracetamol, *Tagamet* for cimetidine and *Valium* for diazepam.

This difference means that doctors wanting to obtain a particular therapeutic effect will have more chance of achieving the intended result if they use a branded drug. If pharmacists are allowed to substitute a generic product even when the doctor has prescribed a brand-named one (an arrangement known as generic substitution), as they are in Canada and all US states under Medicaid subject to the doctor's approval, then the therapeutic effect may not be what the doctor intended. Similarly, if doctors are compelled to use only the generic name (known as generic prescribing) the therapeutic effect may be less certain. Such unintended effects are not always significant, but there are several examples of harm befalling patients in such circumstances. One of the best-known incidents concerned patients with Addison's Disease at the University College Hospital, London, who were unexpectedly found to be no longer responding to treatment with cortisone. Examination showed that the source of supply had been changed, and, whilst the tablets were of an acceptable quality, they had been made in such a way as to lower the 'bioavailability' of the active ingredient. The bioavailability of a substance is the rate and extent to which the therapeutically active substance in a tablet or capsule is absorbed from the product and becomes available at the required site of action.

There are other considerations too. A generic medicine may make up the compound with a different excipient. (An excipient is a medical term for the ingredient in a medicine that accompanies the active substance but has no intended therapeutic effect. It may be a bulking agent or a binder or colouring. The syrup in cough medicine is an example.) Thus, one version of a therapeutically active substance may cause gut irritation whereas another may not. It is no less possible that an excipient, such as tartrazine or gluten, may have toxic or allergic effects on some patients. And a different shape may ease swallowing, or a different coating or flavour promote the patient's compliance and therefore the likelihood that the medicine will have the intended effect. Yet, a good deal of public debate takes place as if generic and brand-named products were identical.

In addition, the use of brand names gives manufacturers a vested interest in their own safety record. Drug companies put considerable resources into making the names of their



products well known. A vital part of such promotional activity is to build and maintain a reputation for quality and safety.

**The Selected List:** In November 1984 the Government announced that a smaller range of drugs would be available under the NHS in seven drug categories: minor pain killers, cough and cold remedies, laxatives, indigestion remedies, vitamins and tonics, and sedatives. In April 1985 a selected list of around 400 products excluded from the NHS came into force. The government hoped to cut the NHS drugs bill significantly, and claimed that savings of about £75m were made. Patients were expected to purchase the products over the counter in retail pharmacies.

In November 1992 the Government announced its intention of extending the selected list. To the original seven therapeutic categories it is to add another ten, including oral contraceptives, drugs for the treatment of anxiety and mental illness, and skin diseases. At the time of writing, the full details of the scheme had not been disclosed, but it appears that items on the new selected lists will not be excluded from the NHS, but rather subject to price guidelines. The new selected list, therefore, appears to resemble the German reference pricing scheme. By February 1994 progress had been slow. Companies selling anti-arthritis products had accepted some voluntary grouping and agreement had been reached on some creams containing non-steroidal anti-inflammatories used to treat skin conditions. The possibility of a legal challenge under the EC Transparency Directive was also delaying progress, on the ground that the negotiations were confidential.

**The Indicative Prescribing Scheme:** The White Paper, *Working for Patients*, published in January 1989 declared the Government's intention to introduce stronger control of prescribing costs in general practice. It noted the wide variation in drug costs from one area to another, from £26 to £48. This was thought not only to reflect differences in population structure and morbidity, but also the attitudes of doctors who, the report claimed, 'have no direct interest in the cost of the drugs which they prescribe'.<sup>4</sup> PACT had been introduced to make GPs aware of the cost of their prescribing and how they compared with other doctors, and indicative drug budgets were designed to add some teeth to these initial measures. The Government declared its objective to be:

to place downward pressure on expenditure on drugs, particularly in those practices with the highest expenditure, but without in any way preventing people getting the medicines they need.<sup>5</sup>

The Working Paper, published a little after the White Paper, declared that, 'It is generally recognised that some prescribing is wasteful or unnecessarily expensive' and repeated the Government's intention to 'place downward pressure on expenditure on drugs in order to eliminate this waste'. It also repeated the assurance given in the White Paper that, 'patients will always get the drugs they need'. The scheme would:

take full account of the fact that some patients ... need a greater volume of drugs or more expensive drugs than others. It will ensure that budgets fully reflect these costs and that there will be no disincentive to practices to accept such patients or to begin to prescribe expensive medicine to existing patients, if there is a clinical need to do so.<sup>6</sup>

The indicative prescribing scheme was first introduced in April 1991.<sup>7</sup> Each practice is given an indicative prescribing amount based on past spending patterns, average costs for the FHSA, special circumstances such as high-cost patients, anticipated changes in demand, and an allowance for the forecast increase in the cost of medicines.

Although the 'indicative drug amount' is not cash limited, financial penalties, such as withholding of remuneration, can be imposed by the FHSA on persistent over-spenders. Each FHSA employs medical advisers to whom GPs can turn for professional advice on matters relating to their prescribing. The medical advisers also draw up prescribing profiles for each practice, set amounts for individual practices under the indicative prescribing scheme and monitor performance. The arrangement for GP fundholders is different. They are given cash-limited budgets which are financed from the overall drug budgets allocated to RHAs.

Any system of monitoring individual performance by comparing it with averages is in danger of producing adverse and unforeseen effects. And there is always a risk that some GPs will seek to avoid the attentions of the regulators by adjusting their prescribing habits in ways that may be harmful to patients, as the BMA warned when the scheme was first proposed. The experience of the De Montford Medical Centre in Evesham provides an example. It followed British Thoracic Society guidelines and prescribed anti-inflammatories for 97 per cent of its asthma patients with the result that its prescribing costs were 368 per cent above local and national averages. Its out-patient referrals, however, were 10 per cent lower than average and, above all, its asthma patients were in good shape. Doctors who stand out from the crowd quickly find themselves under pressure. As Dr Shrewsbury, one of the Evesham doctors remarked, 'Every time the FHSA people see our PACT figures they have a fit. But our audits have shown the increased prescribing costs to be justified. Aggressive therapy has helped keep our patients fit'.<sup>8</sup>

A second example is provided by children who suffer from cystic fibrosis. A survey of 620 parents of children with cystic fibrosis carried out the officially sponsored Clinical Standards Advisory Group, found that 15% reported difficulties in obtaining repeat prescriptions and that in a very few cases (just over 2%) GPs had refused to supply pancreatic enzymes on the ground that they were too expensive. One parent reported:

My GP refused pancreatic enzymes on three separate occasions. He asked me if I knew how much they cost and he thought that with all the other drugs my son was a drain to the NHS. The consultant at the children's hospital has to write to him each time explaining the necessity of enzymes.<sup>9</sup>

Moreover, singling out pharmaceuticals for cost control may, in itself, have perverse effects. As a readily identifiable part of the health-care sector, spending on pharmaceuticals is often earmarked for special control, but the effect on total health care spending may not be a reduction, and in some cases total expenditure may increase. A reduction in the use of drugs may lead to more hospitalisation or surgery. And reduced medication for patients undergoing surgery, for instance, may lead to an increase in costly post-operative complications. The prophylactic use of antibiotics before surgery has been found to reduce

the incidence of wound infections in head and neck surgery, thus cutting total hospital expenditure<sup>10</sup> and a similar result has been found following the prophylactic use of antibiotics before caesarian section.<sup>11</sup>

The NHS is already known to withhold medicines for financial rather than clinical reasons. Examples of the withholding of treatment include drugs of established safety and efficacy for treating patients suffering from cancer and renal failure. Erythropoietin for dialysis patients reduces anaemia, but many NHS patients are denied it because of its cost. The National Federation of Kidney Patient's Associations estimates that only about half the patients who would benefit from erythropoietin are getting it. To circumvent cash limits some hospitals were trying to persuade GPs to prescribe it. A study of 13 European countries by the European Dialysis and Transplant Association found that Britain was the eleventh lowest user. Only Italy and Greece used EPO to a smaller extent.<sup>12</sup> Britain is also a low user of cyclosporin A, an immuno suppressant, for renal transplant patients.<sup>13</sup> A study of 2,590 patients undergoing anti-cancer therapy in France, Germany, Italy, Spain and the UK found that UK doctors prescribed 5HT<sub>3</sub> to 50 per cent fewer patients than the other four nations. UK doctors also gave smaller doses. A single 8 mg injection of ondansetron on the day of cancer chemotherapy treatment is the norm in the UK, but in other countries it is followed up with 2-5 days further treatment with ondansetron to prevent the vomiting often experienced by patients undergoing chemotherapy. The vomiting can be so severe that it results in physical damage including dislocated jaws, yet the guidelines issued to consultant oncologists at London's Royal Marsden Hospital state: 'Ondansetron is undoubtedly an effective antiemetic and has the advantage of being virtually devoid of side-effects. However, because of the significantly higher cost of ondansetron, we feel its use should be restricted'.<sup>14</sup>

These pressures on GPs are reflected in general measures of the rate of absorption of new medicines in Britain. One method is to compare the proportion of the increase in spending on medicines due to new products with the total increase. A study by IMS International found that new products launched between 1987 and 1991 accounted for 17% of the growth in spending on medicines in Britain during the same period. Britain was third lowest of the 19 leading nations studied.

#### *The Manufacturers*

To offer a pharmaceutical product for sale a manufacturer has several obstacles to overcome. First the company must obtain a product licence by demonstrating the safety, quality and efficacy of new products.

Second, all governments decide which drugs they will make available under their national health system. No two systems are exactly alike. Some countries operate 'positive lists', that is every eligible drug is listed, and any other product is not included. In Britain and Germany there are 'negative lists', that is, products *not* covered are listed while anything else is included.

In countries such as France, Italy and Spain which operate positive lists, manufacturers must first obtain a product licence on grounds of safety, efficacy and quality, and then also obtain approval for reimbursement. At this stage governments control the prices they will pay. There is no formal price control in the American private sector, and for practical purposes none in Denmark, but all other European countries control prices.<sup>15</sup>

### *Safety, Quality and Efficacy Regulation*

Before the enactment of the 1968 Medicines Act the only protection afforded by the law to the patient who suffered injury as a result of taking a medicine was the right to sue the manufacturer for negligence. For compensation to be payable, the injured person was required to show that the manufacturer had failed to exercise the ordinary skill and care owed by a person in the business of drug making.

The effects of the drug thalidomide, first revealed towards the end of 1961, brought about a dramatic change in public attitudes which led to the establishment of new regulatory machinery under the 1968 Act. The theory which underlay the new system was that tragedies could be avoided by more thorough testing of drugs, especially on animals, before administration to humans.

In 1968 the Medicines Act established the compulsory regulatory machinery which became operational in 1971 and which remains in place today. The licensing authority consists of the health ministers of the United Kingdom (the Secretary of State for Health, the Secretaries of State for Wales and Scotland, and the Department of Health and Social Services for Northern Ireland). In practice, the Medicines Control Agency is the licensing authority, issuing Clinical Trial Certificates, which grant permission for drugs to be administered to humans, and subsequently Product Licences, which allow products to be marketed.

Medicines are usually divided into three groups: those available on a doctor's prescription only; those obtainable without a prescription but through a pharmacy only; and those obtainable without prescription in any retail outlet. The last two categories are generally called over-the-counter medicines. In most European countries medicines which do not require a prescription are available from pharmacies only, but in Germany, the Netherlands and the UK some are on general sale.

### *Price Control*

The prices of individual pharmaceutical products are not subject to direct control in the UK, but each manufacturer is covered by the Pharmaceutical Price Regulation Scheme which limits the amount of profit a company can earn on its total sales to the NHS. If profits rise above a specified figure, product price reductions may be required and if profits fall below an agreed level price increases may be permitted. The initial price of a new product is not controlled. The scheme began in 1957 as the Voluntary Price Regulation Scheme (VPRS). Prices to be paid by the NHS were determined by reference to export prices, or, where



appropriate, the equivalent of the generic price, or according to a formula taking into account manufacturing, distribution and marketing costs.

In 1969 the VPRS Mark 4 significantly tightened control of pharmaceutical pricing. The VPRS had previously only applied to branded products, but was extended to generic manufacturers who exceeded a specified turnover. And, for the first time, companies were required to submit annual financial returns, to enable the government to judge whether 'excess' profits were being made.

In the face of rising inflation and falling profits the VPRS was eased in 1972, but the Labour Government of 1974 was determined to squeeze the industry. Moreover, between 1973 and 1975, the Monopolies Commission was in dispute with Hoffman-La-Roche over the prices charged for Librium and Valium, and ultimately concluded that in the 'virtual absence of price competition' the company was making excess profits. Against this background, in July 1976 the Secretary of State introduced controls to cut expenditure on promotion from 14 per cent of sales to the NHS in 1975 to 10 per cent by 1979. There was no ban on expenditure above 10 per cent, but it was not counted as an allowable expense in the calculation of profit from sales to the NHS. The current figure is 9 per cent of total sales to the NHS and companies are 'fined' the whole of any excess in spending above 9 per cent.

In 1978 the arrangement was renamed the Pharmaceutical Price Regulation Scheme (PPRS) to reflect the industry's feeling that it was not voluntary. The PPRS was not significantly different from previous arrangements, but it did incorporate a more explicit system of rewards for companies which contributed to the economy by investment or exports. The general thinking underlying the PPRS has been described by a senior civil servant formerly responsible for administering it:

We prefer to look at a company's costs and overall return on investment; on the assumption that if costs and the return on capital are reasonable what the National Health Service pays for the totality of supplies from that company will also be reasonable.

The Department of Health has therefore seen no need to get involved in detailed price fixing. Nor, according to the department, has it been solely concerned with getting the lowest possible prices, but rather pays 'particular attention to the need to give the industry a strong home base and a level of profit which will enable it to pay for the ever more costly and necessary research and development'.<sup>14</sup>

The heart of the system is the annual financial return (AFR) provided by each company with sales to the NHS above a certain level. The AFR must be presented to the Department of Health within six months of the end of the company's financial year and must distinguish between sales to the NHS and other business. Detailed schedules report revenue from sales and the costs of production, distinguishing between NHS and export business. Items like promotional expenditure are fairly easy to allocate, but production plant is rather more difficult. The cost of research and development is also difficult to divide between NHS and export business because it is not related to current products. Capital must be valued at

historic cost, separating fixed assets from current assets and liabilities, and transfer prices (the charges made for supplies obtained from overseas affiliates) disclosed.

The general approach to profits has been that suppliers to the government should earn the same sort of return as British industry in general. Until January 1985 the government fixed an overall return on capital for the industry and then, within this limit, negotiated an agreed return on investment with each company based on its annual financial return and its contribution to the UK economy. Companies were, in the informal jargon of the industry, awarded 'brownie-points' for increased investment, research and development, value added during manufacture, or export achievement.<sup>17</sup>

Each company has been allowed, at the discretion of the Department of Health, to exceed its individual target rate of return on capital up to a ceiling: 10 percentage points above target until March 1984, from that date until the 1986 scheme, by one-third, and subsequently 50 per cent. The band of profit between the target figure and the ceiling is called the 'grey area'. The Department of Health does not normally seek to recover excess profits within this grey area, so long as it is satisfied that the company has improved productivity or increased sales of existing products without price increases. But while profits are within the grey area no price increases are authorised. The Department of Health does not take a view about individual prices, but will refuse to authorise an increase if it forecasts that profits for the year will exceed the company's target.

In July 1986 negotiations on a revised scheme were completed. From October of that year target rates of return on capital were increased slightly, allowing individual companies to fall within the range 16-18.5 per cent. Since April 1988 the target figure has been linked to the average return on capital of British industry using the FT500 index as an indicator, a formula suggested by the industry in the hope of freeing the PPRS from arbitrary political pressure. Until October 1993 companies were allowed to make a return on capital within the range, 17 to 21.5 per cent.

In October 1993 a new scheme took effect. Each company with sales of over £20m per annum has to submit an annual financial return describing its total sales to the NHS, the costs incurred and the capital employed in the form of manufacturing plant and research and development premises.

Companies are allowed a return on capital employed in supplying the NHS within the range 17-21%. The 'grey area' has been replaced by a 'margin of tolerance' of 25% above or below each company's target. New products can be priced at the discretion of the company, and variations launched within five years of the original Product Licence may also be freely priced. All other products require the approval of the Department of Health.

The amount that may be spent on promotion is fixed as a percentage of total sales to the NHS and distribution between companies is based on the following formula:

- i a basic allowance per company of £400,000
- ii a company allowance of 6% of sales to the NHS

iii individual product allowances of £50,000 for three products; £40,000 for a further three; £30,000 for three more; and £20,000 for the tenth and subsequent products.

There are no fines, as under the 1986 agreement.

The research and development allowance is negotiated with each company with a firm indication given one year ahead, and provisional indications for the following two years. The allowance reflects:

i the average spending of the UK industry as a proportion of sales to the NHS

ii investment in the UK

iii each company's global spending pattern on research and development.

From Paternalism  
to Partnership

The doctor-patient relationship has altered substantially since the foundation of the NHS in 1948. At that time it was assumed that the doctor knew best. He or she interpreted symptoms, stipulated a remedy, and the patient took the medicine as prescribed, with little or no effort made by the doctor to explain the risks involved in any particular treatment. In recent years, patients have come to expect more information.

This change is recognised by the BMA in its guide to medical ethics. In the past, says the BMA document:

The doctor, as the expert, used his superior knowledge and made decisions on health care issues which many people could not hope to comprehend. Over many years, this has led to the development of a medical mystique and thus a failure to communicate.

**This attitude cannot continue, says the BMA report:**

Increasingly patients have begun expressing a desire to know what is wrong with them and to understand the action taken by their doctors. Many wish to participate in decision-making ... We are now experiencing a change from paternalism into partnership. Simultaneously, more emphasis is being placed on the patients assuming responsibility for their own health, especially concerning the effects of their own way of life ...<sup>18</sup>

The change is recognised by the NHS Patient's Charter, which took effect in April 1992. The Government states that every person has a right:

to be given a clear explanation of any treatment proposed, including any risks and any alternatives, before you decide whether you will agree to the treatment.<sup>19</sup>

The evolution of the doctor-patient relationship has not been uniform, however. The National Consumer Council, in a report published in December 1991, expressed support for a more participatory doctor-patient relationship but it found that not all patients were being told of the risks associated with drug therapy and, therefore, were unable to reach an informed decision. No drug, insisted the report, is 100 per cent safe and the risks should always be explained to patients.<sup>20</sup>

Nor should the practical difficulties entailed in moving towards a more participatory doctor-patient relationship be underestimated. The relationship with members of the learned professions is different from that between the average customer and the average shopkeeper, but it does not follow that the greater knowledge of the professional should lead to a one-directional chain of command. The purpose of medical training is to enable doctors to be of service. In some cases the doctor will be dealing with patients who they consider to be their social equals, perhaps with an expertise of their own in another sphere. In others, the knowledge imbalance will be considerable and patients may well decide to lean heavily on the doctor, to borrow his judgement as it were. The choice to be made by someone in that



situation is not so much about weighing up the doctor's advice, but deciding which doctor to trust.

Before the imposition of a public sector monopoly it was easier for consumers to make such judgements. People from a poor background, for instance, would frequently choose a doctor who commanded the confidence of the 'gentry' or the middle class. Today, under a uniform system which suppresses comparative information about doctors, it is more difficult, but in the near future perhaps people will come to rely on the recommendation of the Consumer's Association, or the 'seal of approval' of the Patient's Association.

In any event, it is likely that there will always be some patients who are content to be given minimal information because they prefer simply to put their trust in the doctor's skill and judgement. Such feelings should be respected, but by the same token, patients who want to be properly informed should not have their wishes disregarded.

It is not only that patients are entitled to be warned of the risks that they personally face by following a doctor's advice, there are sound clinical reasons for full discussion between doctor and patient. Different people experience different reactions to the same drug and there is more chance of avoiding adverse reactions if the patient's full medical history is presented to the doctor. A hasty, one-sided consultation is unlikely to reveal all relevant facts. Moreover, there is a continuing tendency to demand complete freedom from risk and to call for compensation when someone suffers an adverse reaction. And there is an expectation that regulatory agencies should be able to predict harmful side-effects and ban drugs which cause them. But total freedom from risk is impossible, and the complex risk/benefit balances entailed in modern prescribing can satisfactorily be made only at the level of the individual patient. Regulatory bodies cannot foresee all the possible clinical situations that might arise. The safety of medicines simply cannot be guaranteed before the drugs reach the patient. The balance between risk and benefit, and judgements about the safety of any given medication, are consequently an unavoidable part of the doctor-patient relationship.

Patients, therefore, are inescapably involved in the assessment of the clinical risks they are taking. But this unavoidable reality calls into question our attitude to consumer payment. Such judgements are not easy, yet, if we consider people fit to balance the risk of suffering an adverse reaction or side-effect against the possible benefits of treatment, why is there continuing reluctance to permit people to assess the potential risks and benefits in the light of the cost?

There remains an inconsistency in the public mind. The NHS was founded under the influence of a collectivist ethos which saw the state in the image of an indulgent parent: charged with caring for its child-citizens. For the British of all people to have fallen under the sway of this debilitating doctrine was an historical aberration. Britons have usually thought of themselves as bold, thinking, valuing individuals, invincible in war, magnanimous in victory, kindly towards the underdog, and just in all dealings. This self image is incompatible with the collectivist view that we need to be shielded from the burden of paying for medicines.

The paternalistic ethos which took root during the Second World War has persisted into the 1990s because politicians are afraid to put forward proposals for consumer payment. They know full well that a system of free medical care is unsustainable in the long run. And few politicians or civil servants believe there is an intellectually reputable case for current policies, but there is a marked reluctance to contemplate change because of the perceived political difficulty of withdrawing exemptions. Once a public subsidy has been introduced it is difficult to withdraw it without upsetting the immediate beneficiaries.

The present position is that when political leaders or civil servants can be persuaded to go 'off duty' for a moment and reflect on the wisdom of their policies, few defend them. They know that it is very difficult to mount an intellectually sound defence of the status quo, but are swayed by fear of the political cost of change.

The confused state of public opinion was highlighted during May 1993 when it became public knowledge that the Government was considering the possibility of charging pensioners for prescriptions. Pensioners appeared on TV and radio programmes arguing that they had saved over the course of their lives only to find that they were to be made to pay for a service which they had been told would be free. To some it seemed as if they were being 'punished' for saving, because pensioners who had not saved would be on income support and therefore qualify for free drugs.

Thus, the ironic result of promising free medicines has been to undermine the independent spirit of the people. Staunch Conservative-voting pensioners, with a deep-felt belief in dignity and self-reliance, were the most prominent in complaining about the prospect of paying for drugs. The irony is that high taxes make it harder for people to be self-reliant and it is the provision of 'free' government services which keeps taxes high. Thus, the people who want to enjoy independence, but find it harder to do so because of the high taxation necessitated by high public spending on ostensibly free services, are the very people who demand that drugs should remain free (and taxes consequently high), thereby diminishing their own chances of being independent in old age. The contradictory state of public opinion makes rational change very difficult, but sooner or later Britain's holiday from reality will have to end.

There are some legitimate anxieties. First, there are the poor, who should obviously be protected as at present. Second, any future scheme should also protect people who can afford to pay for pharmaceuticals most of the time but who would be unable to foot the bill during a period of prolonged or intense illness. The proposals in the final Section accommodate both groups.

### Conclusions and Recommendations

#### *Our Recommended Scheme for Britain: Catastrophe Insurance*

First, we propose that the flat-rate prescription charge be abolished and that chemists charge market prices for products. Manufacturers would be free to set their ex-factory prices and chemists and wholesalers free to mark up as appropriate. Price competition among wholesale and retail pharmacists would be permitted. The ultimate aim is the abolition of the PPRS, which will no longer be necessary if the government ceases to be the chief purchaser of drugs.

If accepted, our recommendation would bring about substantial changes for retail pharmacists. They would no longer be paid according to the formula described in Section 1, but would seek low prices from manufacturers and wholesalers and charge the retail prices that competition allowed. We would expect chemists to display their prices outside or just inside the door of the shop so that consumers could readily make comparisons. This arrangement works perfectly well in America and there is no reason why it could not do so in Britain.

Many drugs are inexpensive. The average cost of a prescription in 1991-92 was £7.32, including pharmacists' costs.<sup>21</sup> Some 50 per cent of prescription medicines have a total cost (including the pharmacist's fee, on-cost and container allowances) of less than the current prescription charge of £4.25. Paying out of pocket would not be impossible for most people most of the time. But, some would suffer financial hardship. Two groups would require assistance: (a) those too poor to buy drugs, such as recipients of income support; and (b) people who could afford some expenditure on medicines but who would be unable to pay for very expensive products or pay their way if ill for a prolonged period.

Second, all exemptions should be abolished and replaced by a new system of 'catastrophe' insurance. There is no justification for the current exemptions. Certainly all children should not be exempt regardless of their parents' income, and nor should all elderly people, many of whom are not poor. If drugs were sold at market prices, as we propose, the general rule should be that persons falling below the income support level would qualify for free prescriptions for themselves and their dependants. Special conditions like pregnancy or the current exempt illnesses/disabilities should no longer entitle people to free drugs. Instead the existing pre-payment or 'season ticket' system should be extended so that it becomes a system of voluntary 'catastrophe' insurance for all.

At present it is possible to buy a four-month or one-year pre-payment certificate which, like a season ticket, entitles the holder to free prescriptions for the period covered. With the prescription charge at £4.25, if an individual needs more than four items in four months or

14 in a year then it pays to buy a certificate. If this scheme were continued whilst reducing the scope of the exemptions, and allowing market prices instead of flat-rate prescription charges to be levied, it would mean that a market could develop to cover most people most of the time, whilst providing a stop-loss for those facing larger than normal outlays.

#### *How it would work*

A person buying a pre-payment certificate could be given a plastic 'medicard', like a credit card, which he or she would present to the pharmacist, who would dispense the prescribed medicine without further charge. People below the poverty line would be given the same card as purchasers of pre-payment certificates so that it would not be possible for dispensing chemists to identify who was poor.

At present the value of the pre-payment certificate is linked to the prescription charge. With no such charge it would need to be calculated on a new basis, and as a first step the simplest method would be to maintain the value of the present cash price. Over time it would be necessary to adjust the cost of the 'season ticket' to avoid unduly high subsidisation of drug costs whilst continuing to protect people from catastrophic outlays. The value could, perhaps, be a percentage of average income, or a percentage of the average income of the lowest quintile or decile of wage earners. Or it could be calculated as an actuarially sound insurance premium.

A family rate should be offered so that no family need pay more than the cost of two pre-payment certificates, £121.20 at 1993 prices. A family card could cover parents, plus children under 16 or under 19 and undergoing full-time education.

Some checking would be required. The chemist would need to verify that the name on the prescription matched the name on the medicard (or one of the names, if a family card). In addition, the doctor could write the number of the medicard on the prescription form, just as a retailer writes the number of a cheque card on the back of a cheque. Even with these safeguards the proposed system remains administratively simple.

A slightly similar scheme has been put forward by Dr John Griffin, Director of the ABPI.<sup>22</sup> He has proposed that every adult over the age of 18 years be required to obtain a season ticket from their FHSA as part of a compulsory annual re-registration with their NHS general practitioner. He also recommends a lower value season ticket of £34, based on the national average of eight prescriptions per year at £4.25 each. This scheme would generate additional income of some £1.5 billion per annum.

His reasoning is that patients would be happy to pay more for their health care if they were convinced that their payments were ear-marked for health care. It would also guarantee that all NHS prescriptions would be met for a period of 12 months for all people irrespective of their personal demand for medicines.

Under Dr Griffin's scheme young people under the age of 18 would be exempt from the need to hold a season ticket. Those receiving income support would be required to pay for



their season ticket annually but could recover the cost in whole or part from the Department of Social Security. He also envisages exemption for the very elderly, that is those over 75 years of age.

This scheme deserves serious attention, and it has been pointed out to us that it would have the administrative advantage of tightening up the annual registration of patients with GPs, thus eliminating the risk of the government paying for patients who have died, or moved house without notifying the FHSA. However, we believe its compulsory nature is a disadvantage and we have recommended that people be allowed to choose whether or not to purchase a pre-payment certificate. People who anticipate spending less than the value of the pre-payment certificate should be free to do so.

The advantages of our scheme are:

- Equal treatment for everyone.
- Administrative simplicity.
- The restoration of personal responsibility.
- Reduction of the necessity for government regulation, with its hidden costs and side-effects.
- Protection of the poor, and those temporarily unable to meet unusually large bills for medicines.

We recommend market prices rather than a flat-rate charge for prescriptions in the hope of encouraging price competition between pharmaceutical manufacturers, wholesalers and retailers, which in turn will have the effect of encouraging them to compete with one another by controlling production, development and distribution costs.

The chief disadvantage of our proposal is that there will be no price consciousness by people who have purchased (or been given) a pre-payment certificate. This disadvantage must be set against the projected revenue of nearly £1.5 billion (see below), compared with the paltry £250 million raised at present.

It would also be possible to overcome the lack of price sensitivity above the season-ticket threshold by increasing its price, thereby reducing the number of people who would find it advantageous to buy one and who would, therefore, pay market prices for medicines. It would be sensible for governments to increase the price of the pre-payment certificate in future years until the majority of the population was paying market prices. But if the proposal is to stand any chance of winning public acceptance in the short run there is much to be said for sticking to the price as it stands under existing arrangements.

To ease the impact on consumers, another variation would be to fix the cost of the pre-payment certificate according to income. There could be two rates, one for pensioners and a second higher charge for people in work. Or, a different price could be set for those paying tax at 20, 25 and 40 per cent.

### *The Implications for NHS Revenue*

The total cost of NHS prescriptions supplied by chemist and appliance contractors was £3,343 million in 1991.<sup>23</sup> How much revenue is our proposed scheme likely to generate? First, how much income would be generated if all exemptions were simply abolished? The population of the UK in 1991 was 56,467,000 and each person consumed an average of 8 prescription items. If all exemptions were abolished, if there were no pre-payment certificates available and if everyone paid an average of £7.32 per item (the average cost of prescription items in 1991-92), the total revenue would be about £3,307 million.

How would the pre-payment scheme proposed here affect the potential revenue? If every individual purchased a pre-payment certificate, total revenue would be £3,422 million. However, we propose that there should be a family discount, and this would produce a total potential income of £2,682 million.<sup>24</sup>

In practice, of course not everyone will purchase a pre-payment certificate and it can be expected that people will only do so when they think it will be cheaper. It can also be anticipated that some people will wait until they become ill and then buy a medicard. There can be no certainty about how people will take advantage of the proposed scheme, and so we have prepared estimates in table form based on various assumptions about take-up. Two tables, (Tables 3 and 4), are presented, one for pensioners and one for the remainder of the population. In 1991 there were 10,512,000 persons of pensionable age in the UK, consuming an average 18.2 prescription items per year. There were 33,739,000 people in the intermediate age-group (aged 16-plus and under the pension age less those aged 16-19 and in full time education). They consumed an average of 2.5 items per year.<sup>25</sup>

Any estimate of likely income will have a back-of-the-envelope quality about it, but a fair assumption would be that 70 per cent of pensioners would purchase season tickets and 20 per cent of the intermediate group. According to our calculations that would mean income of about £1,487 million, which is nearly six times more than the meagre £250 million raised by prescription charges.<sup>26</sup>

### *Conclusions*

More and more people undergoing medical treatment think of themselves as consumers rather than patients. They expect to be treated with respect and to be told about the risks associated with medical treatment. This transformation of the doctor-patient relationship from one based on mystique and authority is recognised as a reality by the BMA. We conclude that if consumers are thought, in the light of medical advice, to be capable of assessing the risks and benefits of treatment, then they are surely entitled to be made aware of the cost.

We have, therefore, recommended that the policy of the government should be to move step-by-step towards a market system with the government accepting responsibility for the poor, and for administering a government catastrophe insurance scheme (or pre-payment certificate). As a result, no one will need to spend more than an agreed maximum amount on pharmaceuticals in a year, and a competitive market will be permitted to evolve.

Figure 1

*UK Prescription Exemptions*

Children under 16 and full-time students under the age of 19

Women aged 60 years and over

Men aged 65 years and over

Expectant mothers

Mothers who have a child under one year of age

Mothers of stillborn babies

People suffering from specific conditions:

- 1 permanent fistula (including caecostomy, colostomy or ileostomy) requiring continuous dressing or an appliance.
- 2 Diabetes mellitus
- 3 Myxoedema
- 4 Hypoparathyroidism
- 5 Hypopituitarism
- 6 Addison's disease and other forms of hypoadrenalism
- 7 Myasthenia gravis
- 8 Epilepsy requiring continuous anti-convulsive therapy
- 9 A continuing physical disability which prevents the patient leaving his residence except with the help of another person (this does not mean a temporary disability even if it is likely to last a few months).

War/Service pensioners (for prescriptions needed for treating their accepted disablements).

People receiving income support or family income supplement.

People whose income is not much above the income support level.

People holding pre-payment certificates.

Source: OHE, *Compendium of Health Statistics*, 1992, p. 49.

Figure 2

*International Comparison of Exemptions from the Prescription Charge or 100 per cent Reimbursement*

**Social factors**

Low Income	UK, Italy, Germany, Norway, Denmark, Belgium, Greece, Switzerland, Ireland, Austria
Children	UK, Germany, Norway
Old Age	UK, Norway, Belgium, Spain, Austria
Oral Contraceptives	UK (Sweden and Germany—by some local authorities but not by central government)
War pension	UK, France, Italy, Germany, Belgium

**Medical Conditions**

Diabetes mellitus	UK, Austria, Finland, Italy, Denmark, Belgium, Greece, Sweden, Ireland, Portugal, Spain
Diabetes insipidus	UK, Finland, France, Italy, Denmark, Belgium, Greece, Sweden, Ireland, Portugal
Hypopituitarism	UK, Finland, France, Denmark, Belgium, Portugal
Hypothyroidism	UK, Finland, France, Denmark, Belgium, Sweden
Hypoparathyroidism	UK, Finland, France, Denmark
Hypoadrenalism	UK, Finland, France, Denmark, Belgium, Sweden
Epilepsy	UK, Finland, France, Denmark, Belgium, Sweden, Ireland, Spain
Permanent fistula	UK, Finland, Switzerland, Denmark, Belgium, Portugal
Tuberculosis	Switzerland, Belgium, Portugal

Source: T.D. Griffin, 'An Economist's View of Patient Co-payment for Prescribed Medicines in the European Community' *International Pharmacy Journal*, vol. 6, no.1, 1992, pp. 15-18.

Note 1: Portugal has additional medical conditions, treatment of which is exempt from co-payment, namely renal insufficiency, cancer, Parkinsonism, AIDS, amyloidosis and haemophilia.

Note 2: The age of exemption for children varies. Children under seven years are exempt in Norway; in the UK it is under 16 years; whereas in Italy, the only exemption is for premature babies. In Sweden and Germany local government makes arrangements for further exemptions from co-payment and in the UK, local authorities reimburse the police and firemen and their families for any prescription charge paid.<sup>27</sup>

Note 3: In Denmark and France pensioners and the chronically sick may be exempt under certain circumstances.



**Table 1**  
**Charges and Non-exempt Prescriptions, UK**

	Charges Index* Index: 1979=100	Non-exempt items per person Index: 1979=100	Items
1979	100	100	5.3
1980**	131	84	4.4
1980**	187	84	4.4
1981	179	73	3.9
1982	207	74	3.9
1983	211	70	3.7
1984	229	67	3.5
1985	271	58	3.1
1986	291	56	3.0
1987	302	55	2.9
1988	306	56	2.9
1989	307	54	2.8
1990	309	53	2.8
1991	322	52	2.7
1992	338	51	2.7

Notes: All figures are based on a sample of 1 in 200 prescriptions, excluding items dispensed via prepayment certificates.

\* Figures relate to basic rate at constant prices, as adjusted by the GDP deflator.

\*\* Figures relate to charges introduced in April and December of the same year.

Source: OHE, *Compendium of Health Statistics*, 8th edition, 1992, Box 4.17, p. 49.

**Table 2**  
**Consumer Payment for Pharmaceuticals**

	% of non-hospital medicine costs covered by consumer charges	% of prescriptions exempt from charges
Belgium	24	2
Denmark	38	15
France	30	4
Germany	6	30
Italy	20	44
Spain	10	60
Switzerland	33	2
UK	8	82

Source: Market Access International, *Consumer Co-Payment in Nine European Countries*. January 1992. (The original publication contained an error. The French figure for non-hospital medicines was 18 per cent, but should have been 30 per cent.)

Note: Figures are for 1990, except Belgium (1989) and Spain (1992).

## Notes

- 1 In Acton, *Essays in the History of Liberty*. Indianapolis: Liberty Fund, 1986, p. 200.
- 2 Source: IMS International, quoted in Griffin, J.P., 'Is Therapeutic Conservatism Cost Effective?', Presentation to EFPIA General Assembly, Salzburg, May 1993, p. 1.
- 3 Parliamentary Office of Science and Technology, *Technology and the NHS Drugs Bill*, Technical Report, April 1993.
- 4 Department of Health, *Working for Patients*, CM 555, London: HMSO, 1989, para. 7.13.
- 5 *Working for Patients*, para. 7.15.
- 6 *Indicative Prescribing Budgets for General Medical Practitioners*, Working Paper No. 4, London: HMSO, 1989, p. 3.
- 7 For an excellent discussion of the indicative prescribing scheme see Burstall, M.L., 'Indicative Drug Budgets for General Practitioners: Some Doubts', in Green, D.G., (ed) *The NHS Reforms: Whatever Happened to Consumer Choice?*, London: IEA, 1990, pp. 47-73.
- 8 *MIMS Magazine Weekly*, 12 January 1993.
- 9 Quoted in Griffin, J., *Cheap Prescribing: Can We Afford It?*, London: ABPI, 1994, p. 23.
- 10 Mandell-Brown, M. et al., 'Cost effectiveness of prophylactic antibiotics in head and neck surgery', *Otolaryngology Head and Neck Surgery*, 1984, vol. 92, pp. 520-523.
- 11 Mugford, M., Kingston, J. and Chalmers, I., 'Reducing the incidence of infection after caesarian section: implications of prophylaxis and antibiotics for hospital resources', *British Medical Journal*, 1989, vol. 299, pp. 1003-1006.
- 12 *Nephrology, Dialysis transplantation*, 1991, vol. 6, Supplement 4, pp. 5-29.
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- 14 Lonsdale, J., *Treatment by budget. A study of SHT, prescribing in the UK and Europe*, Isis Research Ltd, BPMRG Meeting, Brighton, April 1993, quoted in Griffin, J.P., 'Is Therapeutic Conservatism Cost Effective?'.
- 15 For a discussion of price control in various European countries see Burstall, M.L., *1992 and the Pharmaceutical Industry*, London: IEA, 1990.
- 16 Marks, D., Speech about the PPRS delivered in Zurich, June 1980, p. 4; Committee of Public Accounts, *Dispensing of Drugs in the National Health Service*, Tenth Report of the Committee of Public Accounts, 1983, p. vi.
- 17 *Dispensing of Drugs in the National Health Service*, Tenth Report of the Committee of Public Accounts, 1983, p. vi.
- 18 BMA, *Philosophy and Practice of Medical Ethics*, London: BMA, 1988, pp. 7-8.

- 19 Department of Health, *The Patient's Charter*, London, HMSO, 1991. p. 9. 23
- 20 National Consumer Council, *Pharmaceuticals. A Consumer Prescription*. London, 1991.
- 21 PPA. p. 9.
- 22 *The Lancet*, 1 May 1993, vol. 341 (Letter to the Editor)
- 23 Office of Health Economics, *Compendium of Health Statistics 1992*, Table 4.26, p. 64.
- 24 The calculation is based on a population of 56,467,000, less 12,216,000 people under 16 or under 19 and in full-time education.
- 25 Office of Health Economics, *Compendium of Health Statistics 1992*, Table 4.24(a).
- 26 One further complication is that many over-the-counter (OTC) products, which consumers would normally buy from chemists, can also be prescribed. It is possible that in some cases consumers who are currently paying privately for OTC products will find it to their advantage to purchase a medicard. If so the burden on the Treasury could increase. It is impossible to make an accurate estimate of this countervailing cost, but we believe it would be small, not least because the OTC products in question are on average low in price.
- 27 Griffin, T.D., 'An Economist's View of Patient Co-payment for Prescribed Medicines in the European Community', *International Pharmacy Journal*, vol. 6, no. 1, 1992, pp. 15-18.

Mr. WAXMAN. Mr. Lott.

**STATEMENT OF JOHN R. LOTT, JR.**

Mr. LOTT. Thank you very much. On January 13th of this year, 565 Ph.D. economists from across the political spectrum, almost all of them academic economists, sent an open letter to President Clinton warning about the dangers of price controls in his health care plan. I am unaware of anywhere near this number of academic economists signing such a letter during at least the last few decades, and we'll find out there are probably even more. Henry Grabowski told me earlier he would have signed if we had asked him to sign earlier. Some of the economists who signed this also had even signed the 1992 Clinton campaign letter endorsing some of Clinton's economic proposals.

Because I believe that this letter is quite relevant to today's discussion of controlling the price of drugs, I would like to read the letter to you:

Dear President Clinton:

Price controls produce shortages, black markets, and reduced quality. This has been the universal experience in the 4,000 years that governments have tried to artificially hold prices down using regulations.

You insist that your health-care plan avoids price controls. We respectfully disagree. Your plan sets the fees charged by doctors and hospitals, caps annual spending on health-care, limits insurance premiums, and imposes price limitations on new and existing drugs.

In countries that have imposed these types of regulations, patients face delays of months and years for surgery, government bureaucrats decide treatment options instead of doctors or patients, and innovations in medical techniques and pharmaceuticals are dramatically reduced. Here in America, the threat of price controls on medicines has already decreased research and development at drug companies, which will lead to reduced discoveries and the loss of life in the future.

In the 1970's, government tried to regulate the price of a simple homogeneous product, gasoline. The result was a social and economic disaster. People were forced to waste hours waiting in lines to purchase gasoline. Long waits for surgery and other medical care will have far more serious consequences.

Caps, fee schedules, and other government regulations may appear to reduce medical spending, but such gains are illusory. We will instead end up with lower quality medical care, reduced medical innovation, and expensive new bureaucracies to monitor compliance. These controls will hurt people, and they will damage the economy. We urge you to remove price controls, in any form, from your health-care plan.

I think this letter is very straightforward and unambiguous. To me, if there is any one thing that we could say economists agree on, it is that government is particularly inept at determining what the correct price of a good should be. Anyone who sat in long lines at gasoline stations during the 1970's can remember how unsuccessful the government was at setting the prices of something as simple as gasoline.



Price controls merely change the form that the price increase takes. In fact, the true price is going to be higher when you have the price control than without it. If you take the price of the gasoline plus the queueing time that people have to spend waiting in line, that total cost to them for buying the gasoline is higher than it would have been otherwise.

It is awful well meaning things that people have to try to control the price of drugs. We're concerned about people being able to purchase it. But you are often going to hurt the very people you are trying to help. I can give you one example.

There has been some effort over the last some years to try to force down the price of AZT, which can help delay the onslaught of AIDS. Even putting aside the recent controversy over AZT's effectiveness, the question is really whether forcing down the price is going to help those who are HIV positive or suffering from AIDS. Surely they will get the price of AZT at a lower price than they would have gotten it otherwise, but what is going to happen to development of a cure?

If a drug company may be 50 percent of the way towards developing a cure or a vaccination for something like this to prevent other people from engaging this horrible agony that is associated with that, they are going to have to think twice now. They are going to see that the expected return that they are going to be getting from creating this type of cure is going to be less than it was previously, and they may get AZT at a lower price than they would have gotten it otherwise, but now their life expectancy is going to be reduced because the probability that they are going to get a cure is going to be eliminated.

The other thing that really bothers me about this discussion is that I think that drug price controls are going to be much more difficult to remove than price controls we've had on gasoline and other types of things in the past. That's because of the long lag time that occurs between when a drug is developed and when it goes through the approval process that is there.

You can imagine 12 years from now when we begin to see a reduction in drugs coming out of the pipeline how difficult it is going to be for a politician to step forward and say, we have a crisis here, we can remove the controls, but it's going to take another 10 or 12 years before we start to see new drugs coming out of the pipeline. Whether or not it is going to be politically possible for somebody to come forward at that time and say, customer and voters out there, you are going to have to put up with high prices for a long time before we possibly begin to see this problem that we have created begin to be relieved is going to be highly debatable, I think.

Mr. WAXMAN. Thank you very much, Mr. Lott. We unfortunately have controls on our time.

Mr. LOTT. I understand.

[The prepared statement of Mr. Lott follows:]

## **Drug Research: Pay Now or Later**

John R. Lott, Jr.\*

On January 13th of this year, 565 Ph.D. economists from across the political spectrum (almost all them academic economists) sent an open letter to President Clinton warning about the dangers of price controls in his health-care plan. I am unaware of anywhere near this number of academic economists signing such a letter during at least the last few decades. Some of the economists had even signed the 1992 Clinton campaign letter endorsing some of his economic proposals. Because I believe that this letter is quite relevant to today's discussion of controlling the price of drugs, I would like to read the letter to you.

### **An Open Letter to President Clinton on Health Care Reform**

Dear President Clinton:

Price controls produce shortages, black markets, and reduced quality. This has been the universal experience in the four thousand years that governments have tried to artificially hold prices down using regulations.

You insist that your health-care plan avoids price controls. We respectfully disagree. Your plan sets the fees charged by doctors and hospitals, caps annual spending on health-care, limits insurance premiums, and imposes price limitations on new and existing drugs.

In countries that have imposed these types of regulations, patients face delays of months and years for surgery, government bureaucrats decide treatment options instead of doctors or patients, and innovations in medical techniques and pharmaceuticals are dramatically reduced. Here in America, the threat of price controls on medicines has already decreased research and development at drug companies, which will lead to reduced discoveries and the loss of life in the future.

In the 1970s, government tried to regulate the price of a simple homogeneous product, gasoline. The result was a social and economic disaster. People were forced to waste hours waiting in lines to purchase gasoline. Long waits for surgery and other medical care will have far more serious consequences.

Caps, fee schedules, and other government regulations may appear to reduce medical spending, but such gains are illusory. We will instead end up with lower quality medical care, reduced medical innovation, and expensive new bureaucracies to monitor compliance. These controls will hurt people, and they will damage the economy. We urge you to remove price controls, in any form, from your health-care plan.

This letter is very straightforward and unambiguous. To me, if there is any one thing that economists agree on, it is that price controls produce shortages and that the government is particularly

\* Lott is the Carl D. Covitz Term Assistant Professor at the Wharton School, University of Pennsylvania.

inept at determining what the correct price of a good should be. Anyone who sat in long lines at gas stations during the 1970's can remember how unsuccessful the government was at setting prices for even a relatively simple homogeneous product like gasoline. After Reagan eliminated gas price controls in 1981, we never again experienced any more gasoline shortages.

Price controls cannot prevent real price increases, but can only change the form that they take. With gas, we paid through the time that we were stranded in lines. For medical care, patients still pay for higher medical care prices with their time by waiting for care — just ask people suffering delays for surgery in Canada or Britain.

For drugs, controls will reduce the number of new drugs, with the resulting loss of lives that those drugs would have saved. Inventing new drugs is costly, averaging \$231 million. In addition to research and development costs, there is the twelve year average delay that new drugs must endure before they get through the government approval process.

Before we can understand why drug companies set the prices that they do, we must understand why we have patents. Patents encourage innovation. Without patents a competitor could produce the new drugs at the cost of production and prevent the drug's inventors from charging a high enough price to cover both production costs and recoup the large develop costs. The temporary monopoly insures the incentives to develop new drugs. Reducing the prices that companies can charge reduces innovation just as surely as reducing the length of the patent life, but regulating individual prices is much more arbitrary.

However, it is politically tempting to force down the prices that drug companies can charge to make drugs more affordable. Yet, while the need to help the poor who are sick today is immediate, the long run cost to forcing drug companies to pay for society's compassion takes the form of fewer new life-saving drugs tomorrow. A better way to help the poor purchase the latest medicines is to use general government tax revenue to subsidize their drug purchases.

Let me take one example. There has for some years been an effort to force down the selling price of AZT, which delays the onslaught of AIDS. Even putting aside recent concerns over AZT's effectiveness, the question is whether those suffering from AIDS really benefit from such a measure. Surely, they will get AZT at a lower price, but what will happen to research for a cure? Depending on how restrictive the controls are, even companies which are most of the towards developing a cure will

have to rethink any additional investments. Those with AIDS should hope that drug companies view inventing the cure as a financial bonanza and not as a prize whose profits will be regulated away.

One of Clinton's major themes is that drug prices are needlessly 32 percent higher in America than they are in Canada. While this figure is exaggerated for political reasons, a difference does exist even if the correct numbers were used. A drug company will sell an already developed drug in Canada as long as they can cover the drug's production costs. In some sense Canadians are "free-riding" off Americans because the drugs were only developed in the first place because of the higher profits expected on American sales. Unfortunately, with price controls all over the world, there are no large markets for us to free-ride on.

While price controls on oil and other products are usually short-lived as people see the havoc created by government intervention, the pernicious effects of drugs regulations are more obscure. With long lags in the approval process for drugs, it will be years before we notice the lack of new drugs.

Even when people eventually realize that controls are preventing new drugs from being developed, it will be very difficult to remove these controls. If controls are removed, there would be a long delay before new drugs start being produced again. It is unlikely that a future presidential candidate will be very successful if he goes before the voters and asks them to endure higher prices for many years before new drugs will again start appearing. Nor is it obvious that such a lifting of regulations will have the desired effect, since the drug companies would have to be convinced that new controls would not be imposed as soon as newly developed drugs hit the market.

In the last year year-and-a-half since then candidate Clinton surged in the June 1992 opinion polls, the sixteen largest drug companies have lost nearly \$100 billion in combined stock market value, and companies began preceiving price regulations as a real threat. As the expected returns to being in the pharmaceutical industry have plummeted, how many future lives have already been lost because the ideas for new drugs have been shelved?

Unfortunately, while to President Clinton it may seem appropriate to make drug companies pay for his programs, if he succeeds, we will all be paying for it long after he leaves office. My fear is that merely the prolonged threat of price controls has already severely damaged what has been one of America's premier industries. In addition, as the open letter to the President states, "the threat of price controls on medicines has already decreased research and development at drug companies, which will lead to reduced discoveries and the loss of life in the future."



Mr. WAXMAN. Mr. Love.

### STATEMENT OF JAMES LOVE

Mr. LOVE. Thank you. My name is James Love. I work for the Center for the Study of Responsive Law, and over the last several years I have been involved with our staff on a series of studies that have looked at the role of the Federal Government in financing the development of new pharmaceutical technologies and have analyzed the ways in which the technology is transferred from the government to the private sector, particularly looking at issues having to do with the price.

I have also been working with a group that is chaired by Professor Peter Arnot (phonetic) that has been looking at the part of the health care plan that looks at the pharmaceutical benefit section and the Breakthrough Drug Advisory Council that is in the plan.

I would like to testify today on two things. One is the role of the Federal Government in the development of new pharmaceutical drugs, and two is the ways that the Federal Government can control prices on the breakthrough drugs that have been talked about so much today.

First, it was our view when we started working on this issue several years ago—many of our statements that have been made at different congressional committees are referenced in our testimony rather than repeated in the testimony—that it was generally underappreciated. The industry has made a lot of the fact that most of the drugs that are approved are financed with private investment, which I believe to be true, but the issue that we have looked at is, where does the government make its investments?

It was always our hypothesis that the government invested its money in areas that were more important therapeutically and for more severe illnesses than the private companies did. As you know, a large number of drugs are approved every year. Very few, however, are therapeutically different from existing drugs which are on the market or for severe illnesses.

One of the studies which we present for the first time in this testimony is a review of all the new molecular entities which were approved by the FDA for the years 1987 to 1991. There were 117 drugs in that category.

We focused on all the drugs in that group which received an efficacy rating of A by the FDA, which was reserved for drugs with significant therapeutic gain or were used to treat severe illnesses such as AIDS or the general E category for severe illnesses. There were 30 drugs in that category. One half of the 30, 15 of the 30, were drugs that were developed with significant involvement by the government in either the preclinical or the clinical stage of development. Some of the data is summarized in table 3 in our testimony.

There are a few other findings in the study that I think are worth repeating. Of the drugs that were discovered first in the United States, and this is shown in figure 1 of our testimony, there was a total of 17 of the 30 priority new molecular entities that we looked at, and 12 of the 17 were developed with a significant role by the Federal Government, which is 70 percent.

Another fact which we found was important is illustrated in figure 2 of our testimony, and that is that the median cost for FDA new molecular entities that were developed with public funds were about three times higher than the median price of the drugs that were developed without public funds. That is to say, that in the drugs we looked at, which were the important drugs that were developed between 1987 and 1991, the ones that were developed with support from the Federal Government were approximately three times more expensive than the drugs that were developed entirely with private funding.

I have also provided to the committee an attachment which provides some other information involving cancer drugs and the general level of government support for R&D, which I won't describe right now because of the shortness in time.

I will say that in terms of the drug review board, we feel, as many people said earlier, that the board has very limited power, which raises questions as to why it's there. We would hope it's not just a window dressing, giving people false assurance or hopes that there is protection from drugs which are priced excessively. We think it's important that the board have the authority to set the price of a drug if they believe it excessive, require compulsory licensing of the technology, or revoke the orphan drug status of the drug.

Thank you.

Mr. WAXMAN. Thank you, Mr. Love.

[Testimony resumes on p. 837.]

[The prepared statement of Mr. Love follows:]

## Introduction

Mr. Chairman and members of the Committee, thank you for the opportunity to testify today on the topic of prescription drug benefits and the Clinton health care plan. President Clinton proposes to insure that all Americans enjoy health care insurance that includes benefits for pharmaceutical drugs. If this new legislation is enacted, it will result in a substantial increase in the demand for pharmaceutical drugs. The United States, however, has no mechanism for reducing the prices of drugs when the prices are excessive. It is essential that this be remedied in the health legislation that you are considering today.

My testimony will address two issues. First, how important is the federal government's role in funding the development of important new drugs? Second, how can the federal government control prices of drugs which are priced excessively.

## The Government's Role in Funding New Drug Inventions

Over the past three years, the Center for Study of Responsive Law's Taxpayer Assets Project (TAP) has undertaken a study of the transfer of government funded pharmaceutical inventions to the private sector.<sup>1</sup> We have provided a number of testimonies and written comments on these issues to various congressional committees, which I will incorporate by reference today.<sup>2</sup>

As a result of our investigations, we believe that the government's role in the development of new drugs is more important than is generally recognized, and that the government has not found a way to insure that prices for government funded pharmaceutical inventions are fairly

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<sup>1</sup>The Taxpayer Assets Project (TAP) was started by Ralph Nader in 1988 to study the management of government owned property, including intellectual property rights from government funded inventions.

<sup>2</sup>On July 29, 1991, TAP provided testimony to the House Subcommittee on Regulation, Business Opportunities and Energy on the National Cancer Institute's Cooperative Research and Development Agreement (CRADA) with Bristol-Myers Squibb for the development of Taxol. On January 21, 1992, TAP presented comments to the Senate Subcommittee on Antitrust, Monopolies, and Business Rights on the Orphan Drug Act and government sponsored monopolies for marketing pharmaceutical drugs. On March 3, 1992, TAP submitted comments on the proposed amendments to the Orphan Drug Act to the Senate Subcommittee on Labor and Human Resources. On January 25, 1993, the TAP presented Testimony to the House Subcommittee on Regulation, Business Opportunities and Energy on private sector pricing of Taxol and other pharmaceutical inventions developed with federal funds. On February 24, 1993, Ralph Nader and TAP presented testimony to the Senate Special Committee on the Aging on the topic of federally funded pharmaceutical inventions.

priced.

Of course the private sector also plays an important role in the development of new drugs, but industry public relations efforts have vastly overstated the industry's contributions.

### *Expenditures on Clinical Trials*

The government does not collect data on private sector investments in drug development, so the public must rely upon the surveys published by the Pharmaceutical Manufacturer Association (PMA), a trade group with an interest in exaggerating the size and importance of its members investments. According to the PMA's most recent survey of industry R&D efforts, the PMA member companies spent \$7.9 billion in domestic R&D efforts in 1991, more than three times their 1981 outlays.<sup>3</sup>

The federal government has also dramatically increased its outlays on health care R&D, including research directed at the development of new drugs. While the federal government does not publish statistics show the portion of its health care R&D expenditures going toward the development of pharmaceutical inventions, it is possible to look at some comparable figures. The National Institutes of Health (NIH) Budget Formulation Office publishes data on NIH expenditures on human use clinical trials, an important and relatively advanced stage of drug development. The PMA also publishes data on its members expenditures on Food and Drug Administration (FDA) Phase I, II, III and IV clinical trials.<sup>4</sup> These figures are reported in Table 1.

NIH expenditures on clinical trials increased from \$495.5 million in fy 1989 to more than \$1 billion in fy 1993, an increase of more than 100 percent in just four years. According to NIH officials, these figures include both expenditures on Phase I, II and III trials, which occur before FDA marketing approval, and Phase IV trials, which occur after FDA approval.

The PMA reports that its members spent \$2.1 billion on Phase I,II and III clinical trials in calendar year 1991, and another \$269.4 million in Phase IV clinical trials. In 1991, the most recent year for which data are available, the NIH expenditures on clinical trials were equal to 24.1 percent of the total of NIH and PMA expenditures combined on clinical trials.

### *1987-1991 Priority Drugs*

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<sup>3</sup>1990-1993 *PMA Annual Survey Report: Trends in U.S. Pharmaceutical Sales and R&D*, Pharmaceutical Manufacturers Association, October 1993.

<sup>4</sup>The NIH figures do not represent all federal expenditures on clinical trials, and the PMA data does not represent all industry expenditures.



NIH outlays represent a significant portion of the total expenditures on clinical trials, but the significance of the government's role is even more important when one examines where the government spends its money. We wanted to test the hypothesis that the government targets its research dollars for more innovative treatments, or for drugs used to treat the most serious illnesses.

The pharmaceutical industry often claims that private investment is responsible for the vast majority of new drugs developed in the United States. This claim, however, is based upon the widest possible definition of new drugs.

From 1987-1991 the FDA gave marketing approval to 2,270 new and generic prescription drugs, approximately 454 per year. Of this total, the majority were for generic forms of existing compounds. Annually only 20 to 30 of the approvals were for what most people would consider a new drug (a total of 117 over five years). Called New Molecular Entities (NMEs), these drugs are distinctly different in structure from anything already on the market.<sup>5</sup>

Moreover, most of the NMEs do not offer any gain in therapy over existing drugs already on the market. Until 1992, the FDA rated drugs on the basis of efficacy, in order to help determine the priorities for the review of applications. An FDA classification of A was reserved for drugs which offered significant gains in therapy. A Class B drug offered modest gains in therapy, and a Class C drug offered little or no advance in therapy. The FDA also gives an E rating to drugs that were used to treat particularly serious illnesses, and a Class AA rating to drugs used to treat AIDS.

Out of the 117 NME's approved between 1987-1991, thirty were Class A, AA and/or E, indicating that they were either the most innovative, (Class A) and/or were used in the treatment of the most serious diseases (Class E or AA). We used this set of drugs to test our hypothesis that the government expenditures on new drug development are targeted toward the most important new drugs.<sup>6</sup>

For each drug in the sample, we investigated the government's role in the discovery of the drug, as well as the pre-clinical and clinical research.<sup>7</sup> We also calculated the wholesale

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<sup>5</sup>Since 1980 the number of FDA NME approvals has ranged from 12 to 30 per year, with an average of 22.5 per year.

<sup>6</sup>There has been criticism of the FDA's A, B and C efficacy ratings from inside and outside of the industry. While the FDA efficacy ratings, which were abandoned in 1992, are imperfect predictors of the ultimate judgements on the efficacy of new drugs, they are *unbiased*, and useful for the purposes of our study, which seeks to draw conclusions about the relative importance of government funded R&D efforts.

<sup>7</sup>Preliminary results of this study, covering only the year 1991, were presented to the Senate Special Committee on the Aging on February 24, 1993.

patient cost of the drug, based upon a completed treatment or one year of treatment, whichever was less.<sup>8</sup> Summary information about each drug is presented in Table 3.

Among the findings of our study are the following points:<sup>9</sup>

- Half of the 30 drugs studied had federal involvement at some stage of their research. These 15 drugs had varying amounts of their R&D performed with federal money. Eleven of the drugs had federally funded research in every stage. This means that the federal government played a role in their discovery, preclinical research and clinical research.
- Drugs developed with federal funding were substantially more expensive than drugs developed without federally funded research. The *median* cost of drugs developed with government funds was \$4,854, nearly three times the median cost of \$1,626 for drugs developed without government funds.<sup>10</sup>
- Eleven drugs were discovered by the federal government or with money from a federal agency. This includes drugs discovered "in-house" - at NIH or one of the Cooperative Research Groups that work under the auspices of the Department of Health and Human Services, or discovered at Universities or non-profit research centers while working under federal grants or contracts, or discovered by a drug company while working under contract from the NIH.
- Seventy one percent (12 of 17) of the drugs discovered in the United States were developed with federal funds.
- Half of the priority drugs (15 of 30) qualified as Orphan Drugs. Two thirds of the government funded drugs (10 of 15) qualified as Orphans. Eleven of the 17 drugs which were discovered in the United States qualified as Orphans.
- All drugs discovered by universities with federal funding were licensed on an

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<sup>8</sup>Calculations for drug costs are based upon wholesale prices, as published in the 1993 *Drug Topics, Red Book*.

<sup>9</sup>Michael Ward, a TAP Research Associate, carried out the individual cases studies. We will provide the committee with an appendix which gives more detailed information on each of the 30 FDA priority drugs.

<sup>10</sup>If the cost of a drug was expressed as a range, the mid-point of the range was used for purposes of determining the median cost. These numbers differ slightly from those reported in James Love's, "The Other Drug War," *The American Prospect*, Summer 1993, due to the use of more recent price data.

exclusive basis.

### **How can the Federal Government Control Prices of Drugs which are Priced Excessively?**

Today the pharmaceutical industry enjoys immense benefits from the federal government. The U.S. subsidizes drug R&D, grants Orphan Drug protections to drugs not protected under patents, and provides a number of special tax benefits and other subsidies. If the Clinton Administration extends prescription drug benefits to all persons, there will be a dramatic increase in the demand for pharmaceutical drugs. It is essential that Congress take this opportunity to create the mechanisms needed to protect consumers and taxpayers against excessive prices for prescription drugs.

Despite early suggestions that the Clinton Administration would create mechanisms for controlling drug prices, there is little in the Administration's proposal to do so. The section of the legislation which creates an Advisory Council on breakthrough drug prices is about the least which could be done. Apparently all this body will be allowed to do is jawbone the drug companies on drug prices. This Advisory Council should have the authority to reduce prices, require compulsory licensing of technology, or revoke Orphan Drug marketing exclusivity, when prices are found to be excessive.

The proposed legislation does allow the Advisory Council to review cost data supplied by the manufacturers of a drug, but is ambiguous as to the board's authority to compel companies to provide that data.

The issue of what information is collected by the government is an extremely important one. Today the drug industry has extremely detailed information on drug prices and revenues, based upon private industry surveys. There is no reason why this information should not be provided directly to the government, where it can be disseminated to policy makers, scholars and citizens who are concerned about a wide variety of public policy issues.

The PMA also sponsors its own survey of industry R&D expenditures. This is currently the only source of data on this important topic. We believe that it is essential for the federal government to collect information on pharmaceutical R&D efforts, organized in such a way as to allow policy makers to better understand the process of innovation in this important field.

It is particularly important that the government take a more pro-active role in deciding what information it needs and what will be made public. Our recent experiences with the National Cancer Institute (NCI) on the fair pricing of Taxol and other drugs were instructive. The government's role in the development of Taxol was extensive -- the government was responsible for the discovery of the drug, for extensive pre-clinical and clinical testing, and had even developed the techniques for manufacturing the drug. When Taxol was approved for sale by the FDA, publicly available data from Bristol-Myers Squibb's supplier indicated that the company would be selling more than 200 kilos of Taxol per year. At the announced

price of \$4.87 per milligram, the taxol product had a wholesale value of \$974 million per year (before discounts). Under a CRADA with NCI, Bristol-Myers Squibb is marketing the drug and has exclusive rights to use all federal research on Taxol in return for, among other considerations, a fair pricing clause. However, NCI did not ask Bristol-Myers Squibb for any of its costs data, and NCI officials indicated that they would not have known what to do with the data if they had received it. The fair-pricing clause was really an empty promise to protect consumers, because NCI never took the steps to become informed in order to make a responsible decision.

In the case of breakthrough drugs, the firm's investment in a particular technology is only part of a larger picture. Most of the cost of drug development is associated with unsuccessful products. The government needs to routinely collect data on R&D investments, organized around important benchmarks in the R&D process, such as the beginning of Phase I or Phase II trials. This data should be available to the public, at least in aggregate form, to help policy makers understand how investments in pre-clinical and clinical research contribute to the development of new therapies. Information about the federal government's role in funding pharmaceutical R&D should be routinely collected and analyzed, both to more fairly evaluate industry assertions about the importance of private investment in the development of new drugs, and to better understand the outputs from public investments. **Indeed, one criteria missing from the Advisory Council on Breakthrough Drugs' list of factors that it should consider in determining the fairness of drug prices is the role of the government in funding the development of the technology.**

It is worth noting that today the only economists who can obtain detailed data on the pharmaceutical R&D process are those who develop consulting relationships with the industry. This lack of independence from the industry is a serious problem that erodes the government's ability to obtain objective disinterested advice and experience on important questions of public policy.

The pharmaceutical industry in the U.S. has much to be proud of, but it must acknowledge the extent of special government subsidies and privileges that most U.S. industries do not enjoy. It is appropriate and responsible to take steps to ensure that government officials have the power to protect consumers from unreasonable drug prices, including prices for drugs developed with public funding.



**Table 1**  
**NIH and PMA Expenditures on Clinical Trials**  
*(millions of dollars)*

Year	NIH	PMA Phase I,II,III	PMA Phase IV
1989	495.5	1,607.2	240.8
1990	609.7	1,808.8	278.8
1991	745.2	2,076.0	269.4
1992	973.2		
1993e	1,011.9		
1994r	1,093.7		

Source: NIH Budget Formulation Office, PMA's 1989-1991 Annual Survey Report, PMA's 1990-1993 Annual Survey Report.

**Table 2**  
**Government Funding of development**  
**of FDA NME Priority Drugs**  
*(FDA Class A, AA and E Drugs)*

Year	1987	1988	1989	1990	1991	Total
Drug Approvals (including generics)	772	751	352	144	251	2,270
NME	21	20	23	23	30	117
Priority NME	2	4	7	7	10	30
Priority NME/ government funding	1	1	3	3	7	15
Priority NME/ no government funding	1	3	4	4	3	15

Notes: Statistics on FDA approvals are given in the FDA's annual Talk Paper on Drug Approval.

Table 3  
1987- 1991 FDA NME Priority Drugs  
(FDA Class A, AA, and E Drugs)

<u>Drug</u>	<u>Efficacy</u>	<u>Priority</u>	<u>Orphan Status</u>	<u>Price</u>
<i>Drugs Developed With Government Funding</i>				
Ceredase	A	A,E	yes	57,960 - 546,000
Nipent	A	A,E	yes	27,418
Foscavir	B	AA,E	no	21,214
Fludara	A	A,E	yes	10,686
Paraplatin	B	E	no	10,820
Supprelin	A	A	yes	4,468 - 6,478
Hexalen	A	A	yes	4,209 - 6,314
Ifex	A	A	yes	4,854
Retrovir	A	A	yes	3,430
Exosurf	A	A	yes	633 - 3,796
Videx	A	A,AA,E	withdrawn	1,745
Ergamisol	A	A	no	1,264
Ganite	B	E	yes	411
Lariam	A	A	no	161
Adenocard	A	A	no	23 - 117

*Drugs Developed Without Government Funding*

Adagen	A	A	yes	138,600
Clozaril	A	A	no	5,694 - 16,443
Sandostatin	A	A	no	11,008
Cytovene	A	A,AA	withdrawn	6,577 - 6,699
Eulexin	B	E	no	2,965
Idamycin	A	A	yes	2,766
Diflucan	A	A,AA	no	810 - 4106
Survanta	C	E	yes	650 - 2,602
Mevacor	A	A	no	701 - 2480
Anafranil	A	A	no	617 - 1478
Nimotop	A	A	no	841
Ticlid	B	E	no	803
Cytotec	A	A	no	657 - 949
Aredia	B	E	no	312 - 468
Ornidyl	A	A,E	yes	140

Notes: Unit drug prices were based upon wholesale price per unit, as reported in the 1993 Drug Topics Red Book (Medical Economics Data: Montvale, N.J.: 1993) or from industry sources. Treatment regimes obtained from industry sources and the 1992 Physicians Desk Reference, Edition 46, (Medical Economics Data: Montvale, N.J. 1992). In all cases we have reported the costs of a completed course of treatment or a year of treatment, whichever was less. FDA efficacy and priority ratings are given in the FDA's annual Talk Paper on Drug Approval.

figure 1  
**FDA NME Priority Drugs Discovered in U.S.**  
(1987 - 1991)

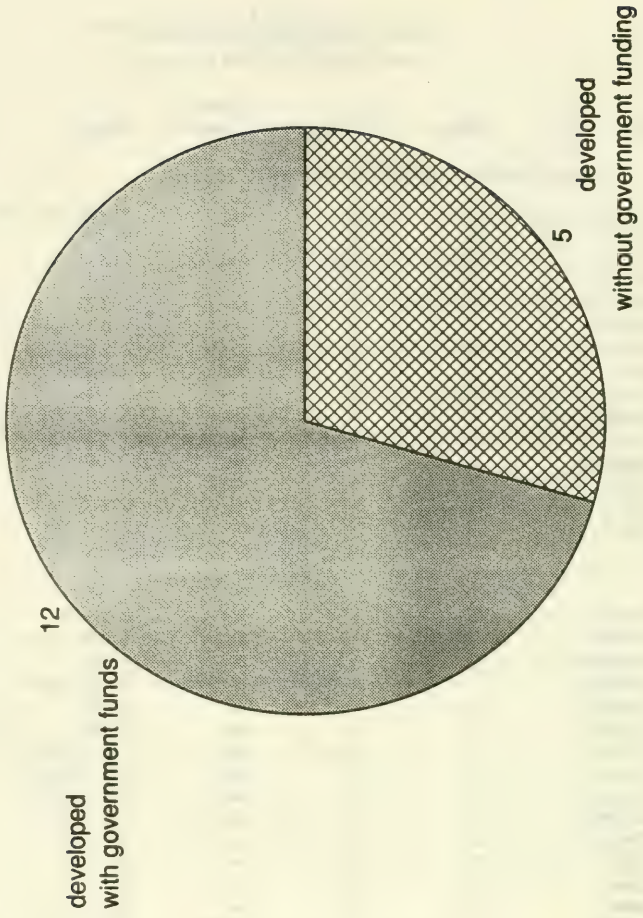
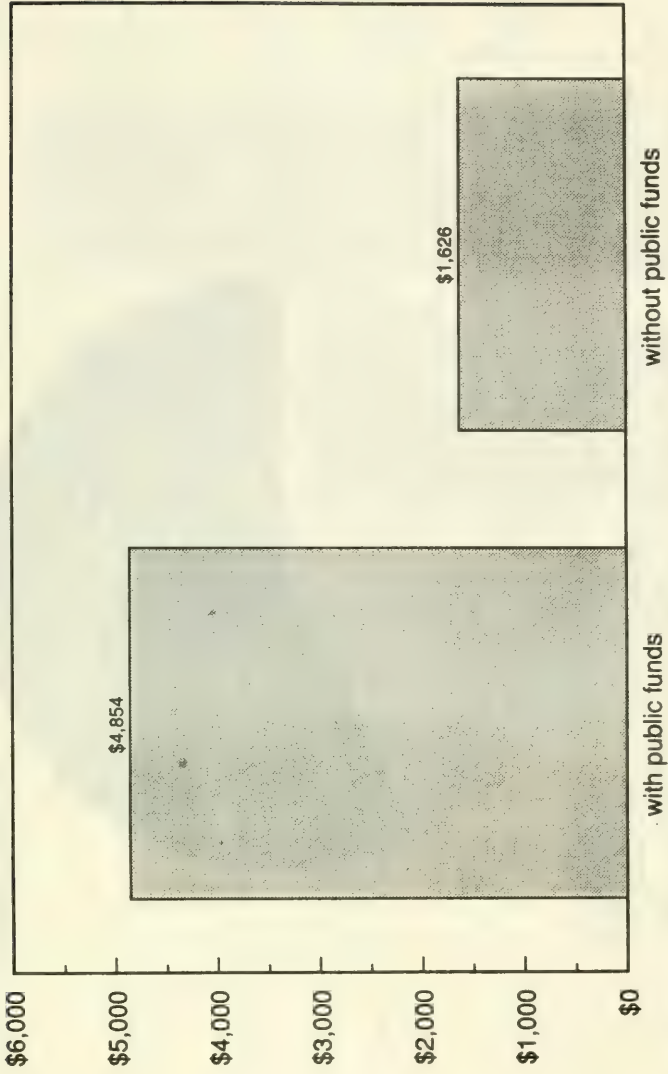


figure 2  
Median Cost of NME Developed With and  
Without Public Funds

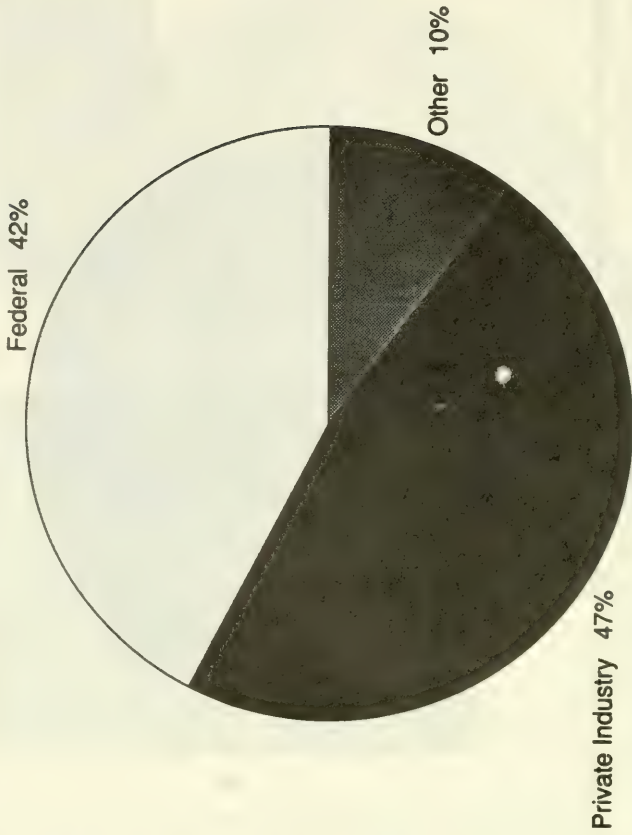


FDA NME Priority Drugs, 1987 - 1991



## ATTACHMENT TO PREPARED STATEMENT OF JAMES LOVE

Figure A-1  
Sources of funding for U.S. Health Care R&D  
(1990)



Source: National Institutes of Health

Figure A-2  
Studies of Drug Development Costs  
(millions of dollars)

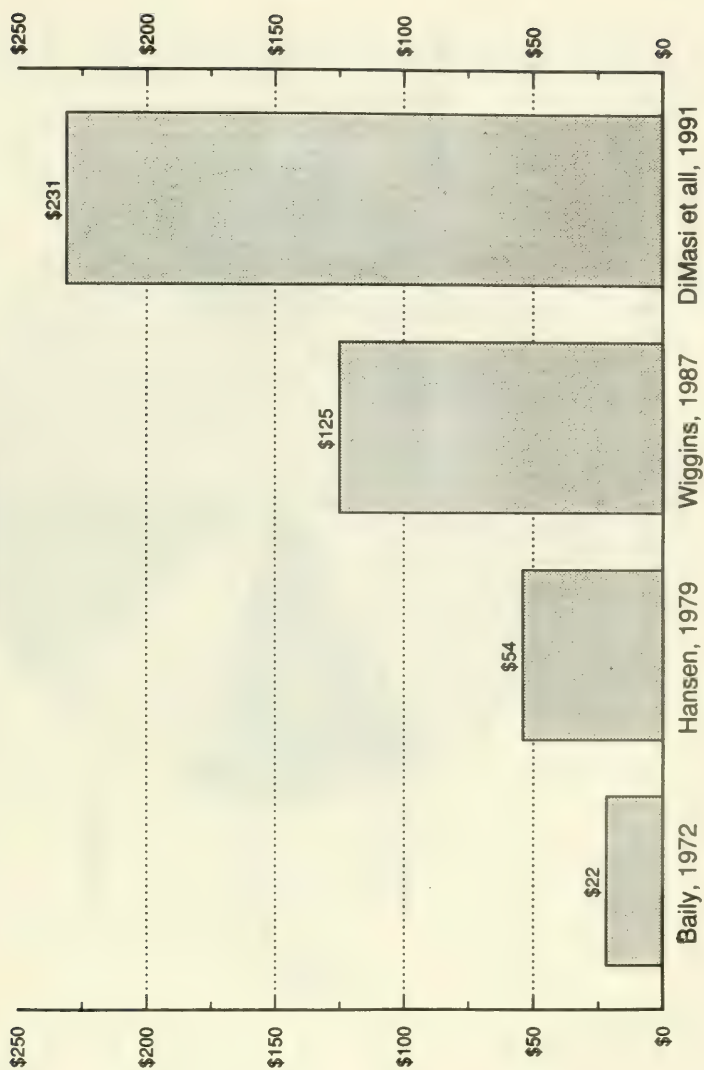
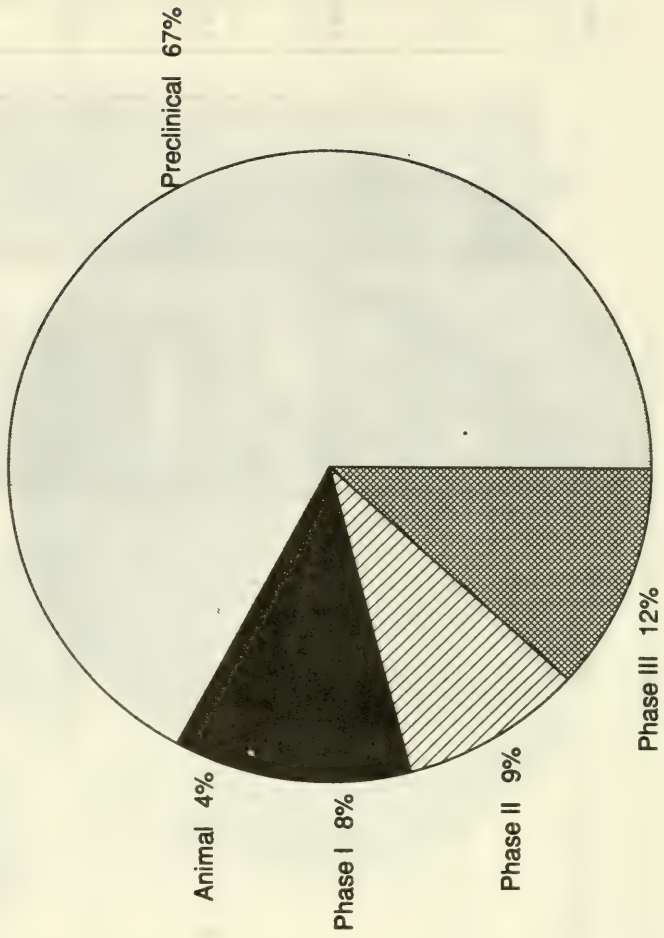
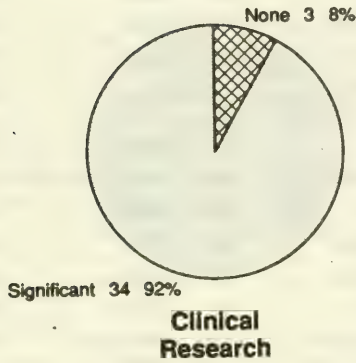
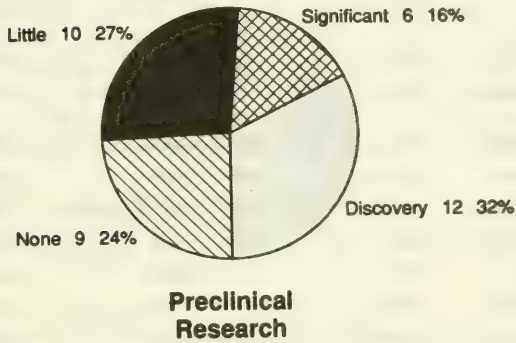


Figure A-3  
Estimated Shares of Drug R&D Costs



Source: DiMasi, Hansen, Grabowski and Langa 91

figure A-4  
**National Cancer Institute Research Role  
for 37 Cancer Drugs**



Source: NCI



**Table A-1**  
**NCI ROLE IN THE DEVELOPMENT OF 37 CANCER DRUGS**

Drug	Discovery Institution	Date of NDA	Marketing Company	NCI Preclinical Role	NCI Clinical Role
Vincristine	Lilly	1963	Lilly	none	major
Pipobroman	NCI	1966	not currently marketed	discovery	major
Hydroxyurea	NCI	1967	Squibb	discovery	major
Cytarabine	Upjohn	1969	Upjohn	significant	major
Procarbazine	Roche	1969	Hoffman-LaRoche	none	major
Mithramycin	NCI	1970	Pfizer	discovery	major
o,p-DDD	NCI	1970	Bristol	discovery	major
Bleomycin	IMC	1973	Bristol	little	major
Doxorubicin	Farmitalia	1974	Adria	little	major
Dacarbazine	NCI	1975	Dohme	discovery	major
Lomustine	NCI	1976	Bristol	discovery	major
Carbustine	NCI	1977	Bristol	discovery	major
Cisplatin	Michigan State	1978	Bristol	significant	major
L-Asparaginase	Cornell	1978	Merck	significant	major
Daunorubicin	Farmitalia, Rhone Poulenc	1979	Ives	little	major
Streptozotocin	NCI	1982	Upjohn	discovery	major
VP-16	Sandoz	1983	Bristol	little	major
Leuprolide	Abbott	1985	Abbott	little	major
alpha-interferon	England	1986	Roche	little	major
alpha-interferon	England	1986	Schering	little	major
Mitoxantrone	NCI	1987	Lederle	discovery	major
Ifosfamide	Asta-Werke	1988	Bristol-Myers Squibb	little	major
Mitoxantrone	NCI	1988	Lederle	discovery	major
Carboplatin	NCI	1989	Bristol-Myers Squibb	significant	major
Flutamide	Schering-Plough	1989	Schering -Plough	none	none

Mr. WAXMAN. Dr. Schondelmeyer.

# STATEMENT OF STEPHEN W. SCHONDELMAYER

Mr. SCHONDELMAYER. Thank you, Mr. Chairman and subcommittee members. I know this is the end of a long day of hearings and I thank you for your patience and tolerance and for permitting me to give my remarks.

I'm a professor at the University of Minnesota and I've spent most of my career studying the pharmaceutical marketplace not only from the perspective of pharmaceutical manufacturers and their interests and needs in the market, but the interests of consumers, of pharmacists, of payors, insurers, government in pharmaceutical products. Those are interests that we need to hear from too.

In my prepared text I cover four basic topics.

The first is the coverage of and expenditures for prescription pharmaceuticals and the likely impact under the health care reform plan.

The second is balancing the expanded coverage that health care reform promises with expenditure growth for pharmaceuticals.

Third are issues related to efficient delivery of pharmaceutical products and services.

And fourth are issues commonly raised by the pharmaceutical industry.

I think the first point I would make is affordability of drug therapy is an issue, and it will be an issue even if we evaluated all the drugs currently in the U.S. market and decided that they were all priced appropriately. Affordability would still be an issue because there are some people in our current system that cannot afford necessary drug therapy for a condition that they have. They simply don't have the resources and our system has not provided them with assistance in acquiring those drugs.

I hear often that competitive price sensitive buyers in the marketplace today are getting better prices. I would argue that there is no buyer more price sensitive than the elderly person on a \$15,000 fixed income who has three chronic diseases and has to spend \$2,000 or \$3,000 of that \$15,000 on prescription drugs. That person is very price sensitive. But we have a marketplace that has been structured so they have been shut out of that marketplace and shut out of the ability to obtain better prices in the market.

I do think changes of individual drug prices are important to the consumer even though they aren't to the individual drug company. We must realize that if we were evaluating the impact of price inflation on a manufacturer's revenue, the companies are right. We should look at the weighted aggregate average increase of all their products and all their markets. That is what we should evaluate. Exactly.

But if we wanted to look at the impact on an individual consumer, I don't know of any patient that needs all of Merck's complete line of products. They need one or two products. I don't know of any patient that has access to all of Merck's channels of distribution. They have access to one or two channels of distribution. To that patient, the price through the only channel they have available is the relevant price. In our marketplace today we still

have about half of all consumers who pay for their prescription drugs out of pocket. They don't have access to Merck's new division Medco or to some of these other organizations that we hear about.

I would like to point out also that I think the expanded coverage promised under the Health Care Reform Act is important and needed and will help provide access to many citizens who don't have it now to needed pharmaceuticals. To balance that, though, we have to look at what will that do to expenditures.

I think we can look at one program in Pennsylvania that was instituted to provide prescription drugs for the elderly in Pennsylvania. When that program first began, the average person in Pennsylvania that was elderly needed 15 or 16 prescriptions per person per year. Today, about 10 years later, the average elderly person in Pennsylvania consumes 25 or 26 prescriptions per person per year. There has been a 67 percent increase in their utilization. In part that's because there was unmet need before and in part I think there may be some overutilization because their drugs are now subsidized and paid for.

Most other industrialized nations have promised or provided some level of health care benefit as well as pharmaceutical benefit to their citizens. Most industrialized nations have at least the majority, if not 80 or 90 percent of their citizens, covered for prescription drugs, but in exchange for that most industrialized nations have placed some limits on the pricing and/or profits of their pharmaceutical products. In fact, I'm not aware of any major industrialized nation that doesn't have some form of price or profit control.

I think it's also important to recognize what is going on in Europe today with respect to pharmaceutical pricing. In the United Kingdom, for example, proposed price cuts have been made and they have also dropped a number of selected drugs from coverage under the U.K. system because they don't have enough resources to pay for those pharmaceuticals.

In Japan there has been a proposed 7 percent price cut across the board and up to 20 percent price cuts proposed for certain drugs.

In Belgium they had a price freeze; in Portugal they had price cuts and a price freeze; in Spain and Italy and France, the same pattern follows.

I would like to comment that I did take the time to look at the new drugs that came on the market at the end of this last year. There were four or five that didn't have any comparison therapy in the market at all, and they came in the market at prices of \$3,000 to \$13,000 per year.

I did look also, though, at some products that had comparison products available on the market, and I found that some of those products came on at competitive prices similar to the comparative products, but other products came on the market at multiples of 8, 10, 20, or 60 times the comparative products already on the market. With that kind of price behavior, I'd have to ask, do we really

have competition in the marketplace today? And if we have competition in the United States and that is the way to go, why is it we are paying higher prices than any other country in the world for pharmaceuticals.

[Testimony resumes on p. 858.]

[The prepared statement of Mr. Schondelmeyer follows:]



## Statement of

**Stephen W. Schondelmeyer, Pharm. D., Ph.D.**  
 Professor of Pharmaceutical Economics

Director. **PRIME Institute**

Thank you Mr. Chairman and members of the Subcommittee for the opportunity to provide input into your deliberations regarding pharmaceutical coverage and health care reform. I am Stephen W. Schondelmeyer, Professor of Pharmaceutical Economics at the University of Minnesota where I serve as Director of the PRIME Institute. This Institute focuses on pharmaceutical research involving management and economics. My education and more than twenty years of experience and research have provided me with a broad and unique understanding of the pricing patterns within the pharmaceutical industry and the drug expenditure patterns of both private and government health care programs.

Others have testified about the impact that health care reform, and its many variations, is expected to have on pharmaceutical companies and their research and development and on the pharmaceutical industry as a whole. My intent is to discuss the implications of health care reform on individual, corporate, and government purchasers of pharmaceutical products in the United States. While in many cases the interests of the producers and the consumers of prescription drugs are similar, there are times when their interests are at odds with each other. In fact, the times when these interests differ most are usually the times when government should appropriately step in to resolve disputes over equitable distribution of rights or efficient distribution of resources in our society.

There are four specific topics related to pharmaceuticals and health care reform that I would like to briefly discuss in my comments today:

- (1) coverage of, and expenditures for, prescription pharmaceuticals;
- (2) balancing expanded coverage and expenditure growth for pharmaceuticals;
- (3) efficient delivery of pharmaceutical products and services; and
- (4) issues commonly raised by the pharmaceutical industry.

#### **Coverage and Expenditures for Pharmaceuticals**

When prescription drugs are necessary and are used appropriately they can be one of the most cost-effective forms of healthcare. There are, however, many barriers to appropriate use of prescription medications. For a growing number of Americans the cost of prescriptions is becoming a major barrier. Practicing pharmacists regularly have patients who do not obtain their prescription because they can not afford it. Other patients may get only part of the prescription filled and take the medication less often than the physician intended, jeopardizing both the drug's effectiveness and the patient's improvement.

Affordability of drug therapy is an issue even if we were to assess the price of pharmaceuticals and declare that all drugs have been priced appropriately. This problem is particularly acute for the nation's elderly. Persons age 65 and over account for 12% of the population and they consume 34% of the outpatient prescriptions. Even though the elderly have greater prescription needs than the rest of the

population, they generally have fewer resources to spend on prescriptions and they are less likely to have insurance coverage for prescription drugs. Contrary to what some would have us believe, a larger proportion of the elderly live with more limited resources than any other adult age group. Heads of households over age 65 had the lowest median income of any adult age group in 1991 earning \$16,975. More than two-thirds of the elderly heads of households had less than \$25,000 in annual income in 1991, when more than 60% of heads of households from all age groups had an income of \$25,000 (Statistical Abstracts of the United States, 1993).

In 1991, the AARP commissioned a study of the need for prescription drugs and drug coverage. Seventy-five percent of the respondents age 45 to 54 had coverage for prescriptions, yet only 55% of those age 65 to 74 and even fewer (40%) of those over age 75 had coverage. This situation is being made even worse by the trend for employers to drop health benefits for their retirees. In 1991 49% of employers reported offering health benefits to their retirees over age 65 and in 1992 only 46% offered such coverage (Foster Higgins, December 1993). Furthermore, not all of these retiree plans included prescription coverage.

The nation's health care program for the elderly, Medicare, does not include outpatient prescription drugs. In contrast, Medicaid programs in all 50 states include prescription drugs even though such coverage is an optional benefit. This widespread coverage of prescriptions speaks loudly about their importance in a comprehensive and effective health benefit plan. At least ten states have developed a drug coverage program for the elderly that is similar to that which a Medicare prescription benefit might offer the elderly.

Since a large portion of the prescriptions needed by the nation's elderly are paid for directly by the senior citizen, the actual price of the medication and changes in that price become critical to access. Some market observers have commented that 'price sensitive' buyers are getting better pharmaceutical prices. I would argue, however, that no group is more price sensitive than senior citizens on fixed incomes. These elderly, and the community pharmacies where they get their prescriptions filled, have routinely been shut out of discounts offered to other 'classes of trade.' Despite suggestions to the contrary, volume is not what accounts for these discounts. Large chains (e.g., Walgreens, Eckerd, or Rite Aid) purchase more than \$2 billion of pharmaceuticals a year, which is far more than any hospital or even a hospital buying group, yet these chains pay a higher price for the same prescription drugs. Not only is the price higher, but the retail class of trade and their out-of-pocket customers also experience higher rates of inflation for prescription drugs.

Manufacturers argue that the only fair way to evaluate prescription price inflation is by measuring change in the weighted aggregate average price for all drugs to all customers in all countries. If one's objective was to determine the impact of price changes on manufacturer's revenue, this method would be exactly right. However, if

one wanted to determine the impact of drug price changes on consumers of prescription drugs a different approach would be required.

In 1993, about one-half of all outpatient prescriptions were paid for out-of-pocket by consumers and were not known to have been covered by a third party program. To the individual consumer, the weighted average aggregate price change is not relevant because the individual may need only one or two specific medicines. For example, a given consumer does not need Merck's entire line of products, nor does that consumer have access to all channels of distribution to which Merck sells drugs. Therefore, the changes in price of individual drugs are quite important to the consumer in today's market.

During 1993, more than two-thirds (68.5%, 137) of the Top 200 drugs increased in price more than the Consumer Price Index (CPI) for all items. The CPI-all items for 1993 increased 2.7%. The inflation rate for pharmaceuticals is the lowest it has been in years. This fact needs to be viewed in perspective, however. First, the overall rate of inflation continues to be even lower than the pharmaceutical inflation rate and this general inflation rate is also at one of the lowest rates in the last two decades. Attached are figures (Figures 1 and 2) showing the parallel movement of overall and pharmaceutical inflation as measured by the PPI and the CPI. Some pharmaceutical firms may have based their 1993 price changes on one of the forecasts of CPI such as the Blue Chip Indicator, which forecast a CPI of 3.2% for 1993. Even if this indicator is used as a comparison, more than 60% (125 of 200) of the Top 200 drugs had price increases to the community retail sector faster than this estimated general inflation rate. Forty-one drug products from the Top 200 had price increases that more than doubled the general inflation rate (i.e., greater than 5.4%) in 1993.

In reply to these findings some manufacturers argue that their price inflation to other settings was lower than the retail inflation rate, resulting in a weighted aggregate average rate at, or below, the rate of general inflation. This explanation is plausible for many manufacturers, but it also leads one to conclude that most other classes of trade routinely have lower inflation rates than the retail class of trade since the prices to these other classes bring the higher retail inflation 'down' to the overall inflation rate. Therefore, the 50% of consumers who pay for their prescriptions out-of-pocket not only have the highest price from the manufacturer, but they also have the highest inflation rate. As long as these two conditions persist it means that the gap will continue to grow.

Establishment of prescription coverage as part of the 'basic healthcare benefit' to be made universally available appears rational, if not inevitable. Coverage of necessary pharmaceutical products and related services to assure appropriate use have been shown to reduce the need for other, more expensive, healthcare services. Coverage of pharmaceuticals for all as part of the 'basic' benefit package is expected to result in a moderate increase in prescription volume. To illustrate how expanded coverage

may result in an increase greater than would be expected from just an increase in the number of people covered, let me describe what happened in the state of Pennsylvania after implementation of the PACE (Pharmaceutical Assistance Card for the Elderly) program. The elderly in the first year (1984-85) of the PACE program received 15 to 16 prescriptions per person per year. Today, the average PACE recipient receives 25 or 26 prescriptions per year. In other words, prescription drug coverage resulted in PACE recipients obtaining 67% more prescriptions than when such coverage was not available. Some of this new prescription use may have been for previously unmet needs, while some may be for unnecessary prescriptions. However, the PACE program actively manages the prescription benefit and has a leading-edge prospective drug utilization review process which helps to insure appropriate drug use.

To summarize, affordability of drug therapy is a major problem for those least likely to have the resources to purchase or have coverage for pharmaceuticals. Consequently, the 'basic' benefit package should include outpatient pharmaceuticals. Universal coverage of pharmaceuticals will result in an expanded volume of pharmaceutical use, some of which will be necessary and appropriate use and some which is not.

### **Balancing Expanded Coverage and Expenditure Growth**

As previously noted the coverage of pharmaceuticals is expected to result in increased prescription volume. Estimates of this expansion vary from 2% or 3% to as much as 15% to 20% of total outpatient prescriptions. In part, this expansion occurs because the basic market mechanism is disrupted. That is, the price-feedback relationship does not determine volume of prescription use. Because pharmaceuticals are a necessity, rather than a typical consumer good, this 'subsidized access' becomes very important. To the individual consumer, the price is no longer very transparent. Physicians are also known to be generally unaware of the relative cost of prescription drugs. How can the price-volume relationship function without informed consumers and physicians?

One of the most basic conditions necessary for competition is a market where consumers have perfect, or at least very good, information on price and quality of the products and services being purchased. Increasing the transparency of pricing in health care at all levels is relatively easy to accomplish and will help make all purchasers be more cost conscious. Pharmaceutical manufacturers should be required to make their prices and pricing policies to all channels of distribution publicly available. Improved access to pricing information should increase competition.

Most other industrialized nations have provided for pharmaceutical coverage for the majority or, in some cases, all of their citizens. The coverage rate for pharmaceutical expenditures ranges from 60% in a few countries to nearly 100% in others. In exchange for the volume expansion resulting from this pharmaceutical coverage



guarantee, nearly all industrialized countries have expected price or profit concessions from pharmaceutical companies. Studies by the GAO and other suggest that the United States pays, on average, more for the same set of pharmaceuticals than any other country in the world. The U.S. was found to be paying one-third more than Canada and 50% more than the United Kingdom.

In addition to the realization that most other countries are paying less for identical drug products, it has become apparent that other countries are actually demanding drug price decreases and not just slowed inflation rates. In fact, in the last year the following price concessions were proposed or implemented: the United Kingdom proposed price cuts and dropped a number of drug products from coverage; Japan proposed a 7% price cut across the board and up to 20% price cuts for specific drugs; Belgium had a price freeze in 1992 and reports that drug companies may now request price increases; Portugal cut prices 2.85% and froze prices for another 9 months; Spain cut prices about 3% and plans to freeze prices until April 1995; Italy proposed a 5% price cut and dropped a number of other drugs from coverage; and France negotiated prices based on price-volume trade-offs (Scrip: 11-26-93, 1-14-94, 1-18-94, and 1-21-94). Various countries have attempted to manage expenditures by negotiating drug prices or profits, limiting drug promotional expenditures, or limiting drugs that will or will not be covered.

### **Efficient Delivery of Pharmaceutical Products and Services**

With these actions by other governments in response to expanded coverage, one must step back and examine the options being considered for pharmaceuticals under health care reform in the United States. First, one can ask "If competition is the means to manage drug expenditures, why is it that the U.S. with its 'alleged' competitive pharmaceutical market has higher price levels than most other industrialized countries? If competition was working wouldn't our prices be closer to, if not lower than those found in other major Western countries? If the rest of the world continues to squeeze pharmaceutical prices and only one major market does not have an effective price-feedback process in place, where can we expect pharmaceutical prices to continue to grow? -- the United States. The step of price review and expenditure management seems eminent if the U.S. is to slow the overall rate of growth in healthcare.

Drug manufacturers have been complaining 'Why pick on us? Price controls don't work.' One does not have to look far to realize that both public and private healthcare systems have expenditure and price management mechanisms in place for hospitals, nursing homes, physicians, clinical laboratories, pharmacists, and many other health products and service. In actuality, pharmaceutical firms are in one of few the sectors that had escaped cost containment the longest.

Certain policymakers and much of the drug industry advocates competitive mechanisms as the solution to healthcare and drug expenditure growth. Using the rhetoric of competition to argue for no expenditure or price constraints, pharmaceutical companies come back to policymakers on another day and ask to have their patents extended. Patents grant a monopoly which allows one protection from competition. This comment is not meant to be a challenge of the role of patents, per se, but rather to point out the ironic nature of the arguments manufacturers make with respect to increasing competition in the market while at the same time they advocate policies that would substantially lessen their own competition.

Major pharmaceutical companies are engaging in other anti-competitive behaviors such as the acquisition of generic pharmaceutical firms. A large share of the U.S. generic pharmaceutical market is now owned, operated, or controlled by the brand name firms. The following quote from a trade journal (Scrip, 1-7-94, p.18) illustrates the anti-competitive influence of this behavior. "In a pre-emptive move, Syntex itself began marketing generic naproxen, through its affiliate, Hamilton Pharma, in October 1993. NatWest Securities analyst Jack Lamberton told Scrip that Hamilton had filled the (inventory) pipeline and may be able to dominate the generic naproxen market this year . . ." Certainly not all activities of brand name firms with respect to generics is anti-competitive, but such arrangements create new opportunities for legal, and illegal, market control strategies that were not previously available.

Other drug manufacturers have recently ventured into vertical integration in the marketplace by purchasing pharmacy benefits management firms and pharmacy distribution systems. At least one pharmaceutical company has proposed that a private pharmacy benefits management firm be contracted to operate what would otherwise be the Medicare drug program. Coincidentally, the firm making this proposal now owns a major pharmacy benefits management firm. Another ironic twist of the market is that same brand-name pharmaceutical manufacturer advocating a pharmacy benefit management company to implement a Medicare prescription benefit which would use restrictive formularies, drug therapy guidelines, therapeutic interchange, aggressive generic substitution, and other such drug cost management tools. These are mechanisms which the Pharmaceutical Manufacturers Association has long argued against. Have manufacturers changed their policy positions in these areas? How do they explain these new positions to groups such as the 'Rainbow Coalition' whose endorsements of PMA policy were sought under the guise of avoiding 'second-class' healthcare from formularies, generics, and therapeutic interchange?

Other firms have suggested that if a pharmaceutical benefit is established under Medicare that such coverage should be administered through private managed care plans. This proposition deserves examination. The Citizens Fund in November 1993 released a report which documented that commercial insurers use more than 36 cents of every health care dollar for administrative and profit costs. All insurers averaged about 12 cents out of every dollar and Medicare administrative costs were 2.1 cents

out of every dollar. This would suggest that Medicare is more efficient at administering the health benefit for the elderly than the private marketplace.

Managed care plans often compare their cost for pharmaceutical benefits to the cost of such benefits in the open fee-for-service market. There are a number of factors which serve to distort these comparisons. First, the managed care market usually has a select, and healthier, working population while national statistics used for comparison include the unemployed, sicker and low income populations. Second, managed care plans usually report the cost of pharmaceutical benefits for which they paid, but they do not capture or report the cost of uncovered pharmaceuticals that the person may pay for on their own. Managed care usually excludes certain drugs such as cosmetic therapies, oral contraceptives, or diet aids. Also, managed care cost reports do not usually include expenditures for prescriptions which cost less than the plan's deductible or copay amounts.

Interestingly, only a small percent (less than 5%-7%) of HMOs operate pharmacies in-house rather than contracting out for pharmacy services. This behavior would suggest that HMOs, in general, cannot deliver pharmaceutical products and services more efficiently than community pharmacies in a competitive retail market. Also, some managed care programs have negotiated rebates, based in part on market share movement, which in most cases relies heavily on community pharmacies to implement and insure compliance among patients and physicians. The rebates received by managed care programs if paid in most other industries would be labelled as 'kickbacks', but they seem to have been legitimized in this market because they 'appear' to create competition and give lower prices. Indeed, to the managed care programs with such rebates their net drug cost is lowered. It is not clear what managed care organizations do with these 'off-budget' rebate dollars: return them to the consumer through lower premiums, use them to develop or pay for other programs, retain them as profit, or some combination of the above. If consumer benefit is the intent of these rebates, policymakers should consider requiring that drug rebate dollars be audited or reported in the managed care organization's annual report.

The other concern about generalizing managed care's apparent success in managing pharmaceutical benefits is that a major factor in their success has been to use their enormous market clout to exact 'marginal prices' in the form of discounts from both pharmaceutical manufacturers and community pharmacy providers. This strategy has worked while aggressive, deep discount managed care has been a small part (10%-25%) of the outpatient prescription market.

However, if managed care organizations using this approach were to be given a large share of the pharmaceutical market (i.e., 50% to 90%) under health care reform, they would be faced with producers (drug manufacturers) and providers (community pharmacies) whose marginal price has now become their average cost (or close to it).

Producers and providers who try to continue operating at the former small-volume, low margin prices will soon be driven out of the market and managed care organizations will be left with a few larger producers and providers who have equal or greater clout to the managed care firm. These surviving producers and providers will have to charge their average cost to the dominant (70% to 90%) managed care market and managed care's pharmacy cost will be higher than what was projected and used as the basis for favoring managed care pharmacy systems. This discourse on managed care pharmacy is not meant to argue against any form of managed care pharmacy benefit, but it is presented to urge serious caution against singular and simplistic proposals that do not account for the long term dynamics and equilibration of the market.

### **Issues Commonly Raised by the Pharmaceutical Industry**

A number of issues are commonly raised by the pharmaceutical industry regarding the potential impact of healthcare reform on the pharmaceutical market. Topics frequently discussed include loss of investment and capitalization, the cost of research and development, and price controls on pharmaceuticals and especially new drug products. With respect to the market capitalization issue, the drug companies appear to promote one profile in Washington and a different profile on Wall Street. Actually some Wall Street analysts had suggested that drug company stocks in 1992 were trading at inflated P/E ratios compared to the rest of the market, before the decline in market capitalization that began prior to the election of the present Democratic administration. One analyst (Value Line Investment Survey, Nov. 5, 1993 as quoted in The Pink Sheet, Jan. 10, 1994) has estimated the P/E ratios declined from 20 prior to the decline and have settled out recently at an average P/E of about 16.

One of the trade publications (Scrip, Jan 14, 1994, p. 16) reported on an Ernst & Young study of biotechnology investment in 1993 versus 1992. The findings showed biotechnology investment up 21% in 1993 over 1992. Although about 10% of the investment came from PIPEs (private investment in a public entity), this did not explain all of the growth in 1993. The Ernst & Young report is quoted as saying "Overall, the biotech industry is poised for a healthy 1994 in spite of the rapidly changing healthcare and political environment worldwide." Another source (The Pink Sheet, Jan. 17, 1994) suggests "Despite the continuing soft market for biotechnology stocks, there are clearly still sources of funding available for biotechnology." The 1993 biotech investment performance and the biotech outlook, hardly show evidence of the 'doom and gloom' being talked about in Washington.

The pharmaceutical industry is to be applauded for their record of research discoveries. Recently, however, some of their claims don't quite add up. For example, we are told on the one hand that pharmaceutical companies pay for about 90% of the drug research and development implying that most new drugs brought to market are the fruits of research within drug companies. On the other hand, the



industry rarely discusses the proportion of their new products that were licensed in from outside sources versus those discovered in-house. Data on this subject is not easy to find, but we have a couple of indications regarding the proportion of new drug projects and approvals which are actually licensed-in. These drugs may be acquired from individual scientists, universities, research institutes, biotech companies, start-up firms, other domestic or foreign companies, or government research programs such as the National Institutes of Health (NIH).

The OTA Study of Pharmaceutical Research & Development reported that for drugs approved between 1983 and 1986, only about 50% of all NCE (new chemical entity) investigational new drug applications were for self-originated drugs. This would imply that nearly 50% of these NCE INDs were for licensed-in pharmaceutical products. A recent article in a trade publication (Scrip Magazine, January 1994, p.45) reports that for the top 50 pharmaceutical companies, 964 of 3,025 (32%) R&D drug projects were licensed-in products. The high proportion of licensed-in new products raises the question: 'What is the role of licensed-in products and how should this affect pricing and reimbursement considerations?'

This brings me to the final issue related to pharmaceuticals and healthcare reform. To guarantee prescription coverage for all, or most, pharmaceuticals and not have some expenditure or price control on new drug prices would be to create an open-ended checking account for the pharmaceutical industry. The U.S. government should seriously evaluate potential industrial development strategies for fostering and maintaining innovation and research in the U.S.-based pharmaceutical industry. A laissez-faire or 'hands-off' approach to the pharmaceutical market will likely be disastrous to state and federal governments' long-term deficit problems. This hypothesis can be illustrated by reviewing new drugs approved or introduced in 1993.

The FDA approved 25 new molecular entities in 1993 (The Pink Sheet, January 10, 1994, pp.6-9). Each of these products were reviewed to determine which had been marketed and thus had established prices. In early January 1994 about one-half (13) of these products had been marketed. Also 23 'important' biologicals were approved by FDA in 1993 (The Pink Sheet, January 17, 1994, p.9). In Figure 3, attached, five drugs are presented which were new 'breakthrough drugs in their respective therapeutic categories. The cost of a course of therapy (or one year for maintenance drugs) ranged from about \$3,000 for Metastron (treatment for bone pain) to over \$13,000 per year for Betaseron (treatment for multiple sclerosis). Each of these drugs was a significant advance and there were no similar drugs to compare these prices against. Other methods could be used to assess these prices including cost-benefit or cost-effectiveness analysis, cost of research and development, market valuation, and prices in other countries, if on the market in such countries. Particularly, for these breakthrough drugs the issue is not so much the price level, but was the pharmaceutical company able to recover its research and development costs plus a reasonable return.

Other new drugs introduced in 1993 had other therapies in the same therapeutic category which could be used to gauge the reasonableness of the introductory price level. Figures 4 and 5 report five new drug entities introduced and their price per similar course of therapy for other drugs in the same therapeutic class. The new drug prices ranged from 67 times the comparison drug's price to a price equivalent to the comparison drug's price. Lovenox, a new antithrombotic agent is priced at 11 times the price of branded Heparin and 67 times the price of generic heparin. This pricing pattern appears to warrant further examination. Other prices appeared much more reasonable. For example, Claritin was priced almost identical to Seldane and Hismanal, even though Claritin may have certain safety advantages over these other agents.

A new antipsychotic drug, Risperdal, was approved in 1993. The company in explaining their pricing strategy compared the price to that of Clozaril, despite the fact that a member of the FDA Psychopharmacologic Drugs Advisory Committee commented that the drug has "not proven to be more effective than haloperidol and should not be equated with clozapine" (The Pink Sheet, Jan. 10, 1994, p. 4). The FDA approval letter even warned Janssen against 'presentation of data that conveys the impression that risperidone is superior to Haldol or any other marketed antipsychotic drug product with regard to safety or effectiveness' (The Pink Sheet, Jan. 10, 1994, p. 4). Based on these statements from FDA officials comparison of Risperdol to Clozaril even for pricing would appear to be questionable. The Risperdol price was found to be 2 times the branded Haldol product and 8 times the price of generic haloperidol (Figure 6).

Two new anti-epileptic products were priced at 4 to 48 times the price of other anti-epileptic therapies already on the market, Figure 7. Perhaps one of the most troubling pricing strategies is the introductory price of a new salt of diclofenac. The potassium form was approved in 1993 as the trade name Cataflam. This product made by Geigy was priced about 1.4 times the price of the sodium salt of diclofenac (Voltaren) which is also made by Geigy and is about to go off patent. In comparison to other anti-arthritic agents this new drug's price ranged from 1.8 to 21 times more expensive per day of therapy (Figure 8).

Some of these new drug introductory prices have to raise questions about whether the market is really competitive for new compounds and whether the market has or will set reasonable prices for new drugs, salts, dosage forms, or strengths.

Figure 1

**Consumer Price Index Annual % Change:  
Rx Drugs vs. All Items - 1980 to 1993**

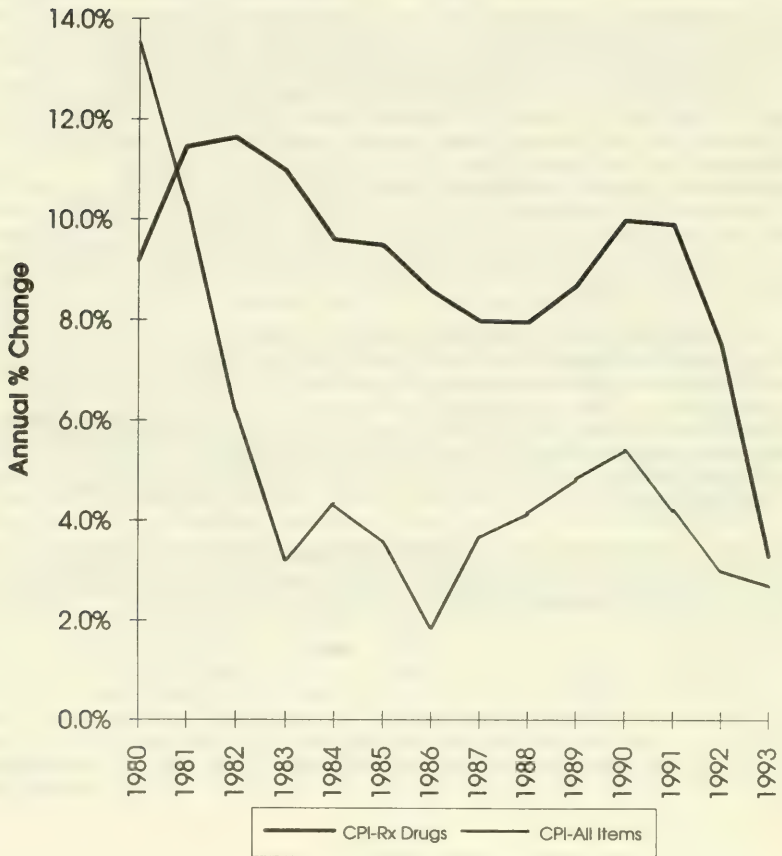


Figure 2

**Producer Price Index Annual % Change:  
Rx Drugs vs. Finished Goods 1980 - 1993**

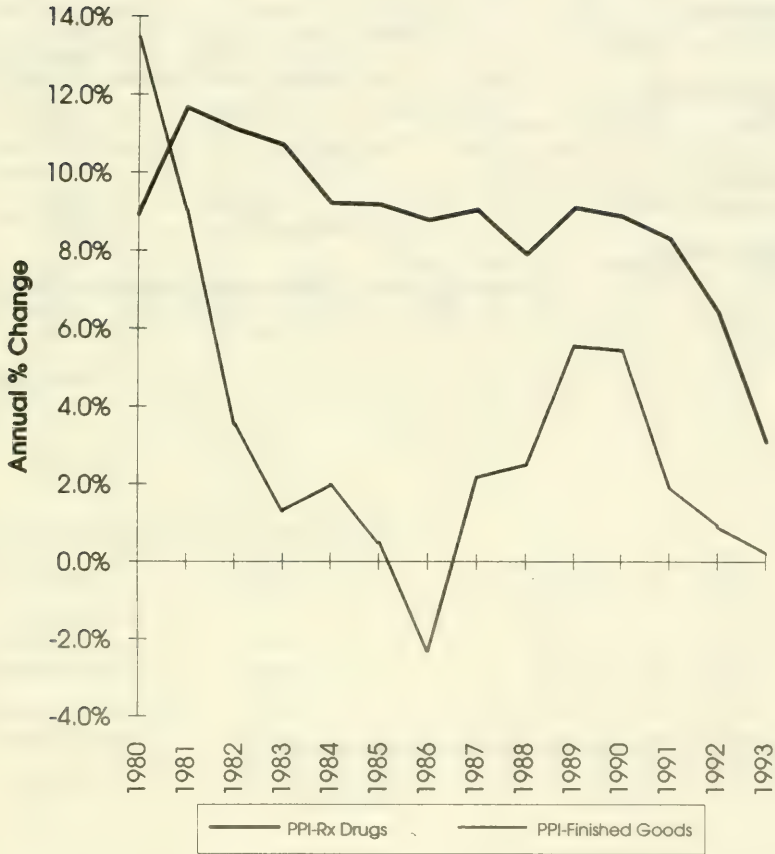




Figure 3

## Cost of 1993 New Drugs with No Comparison Drug

<u>Therapeutic Use</u>				<u>Daily Dose</u>	<u>\$/Day</u>	<u>Duration</u>	<u>\$/Course</u>
<u>Brand/ Generic</u>	<u>Company/ Date Appr.</u>	<u>Dose Form/ AWP/pkg</u>	<u>Strength/ Pkg Size</u>	<u>Typical/ Max.</u>	<u>Typical/ Max.</u>	<u>(days) Typical/ Max.</u>	<u>Typical/ Max.</u>
<u>Cystic fibrosis</u>							
Pulmozyme	Genentech	inj	2.5 mg/2.5ml	2.5	\$32.40	365	\$11,826
dornase alfa	12/30/93 - Bio		30	2.5	\$32.40	365	\$11,826
<u>Multiple Sclerosis</u>							
Betaseron	Chiron/Berlex	inj	0.3 mg/vial	0.25*	\$72.00	365	\$13,140
interferon, Beta	7/23/93 - Bio		1	0.3	\$72.00	365	\$13,140
				(* must use 0.3 mg vial)		(used every other day)	
<u>Leukemia (hairy cell)</u>							
Leustatin	Ortho Biotech	inj	1 mg/ml	6.3*	\$480.00	7	\$3,360
cladribine	2/26/93 - 1P		10	10	\$480.00	7	\$3,360
				(* must use 10 ml vial)			
<u>Bone Pain</u>							
Metastron	Medi-Physics	inj	1 mCi/ml	4	\$740.00	4	\$2,960
strontium-89 Cl	6/18/93 - 1P		10	4*	\$1,850.00	4	\$7,400
				(*may waste 10 ml vial per use)		(given every 3 months)	
<u>Alzheimer's Disease</u>							
Cognex	Parke-Davis	cap	30 mg	120	\$4.39	365	\$1,603
tacrine	9/9/93 - 1P		100	150	\$5.49	365	\$2,004
			40 mg	120	\$3.29	365	\$1,202
			100	160	\$4.39	365	\$1,603

\* Cost as of 12/31/93 expressed as \$ at average wholesale price (AWP).

Figure 4

## Cost of 1993 New Drugs versus Comparison Drug

<u>Therapeutic Use</u>		<u>Daily Dose</u>		<u>\$/Day</u>	<u>Duration</u> (days)	<u>\$/Course</u>
<u>Brand/ Generic</u>	<u>Company/ Date Appl.</u>	<u>Dose Form/ AWP/pkg</u>	<u>Strength/ Pkg Size</u>	<u>Typical/ Max.</u>	<u>Typical/ Max.</u>	<u>Typical/ Max.</u>
<u>New Antithrombotic</u>						
Lovenox	RP Rorer	inj	30 mg/0.3ml	30	\$14.41	10
enoxaprin	3/29/93 - 1P	\$144.08	10	30	\$14.41	10
<u>Compared to:</u>						
Heparin	Upjohn	inj	5000 U/ml	5000	\$1.28	10
heparin sod.		\$12.81	10	5000	\$1.28	10
Heparin	Elkins-Sinn	inj	5000 U/ml	5000	\$0.22	10
heparin sod.		\$2.15	10	5000	\$0.22	10
<u>Price differential:</u>						
11.2 to 1 and 67 to 1						
<u>New Pneumocystis carinii pneumonia therapy (e.g., secondary to AIDs)</u>						
NeuTrexin	U.S. Bioscience	inj	25 mg	50	\$83.28	21
trimetrexate glu	12/17/93 - 1P	\$2,082.00	50	50	\$83.28	21
<u>Compared to:</u>						
Septra	Burr. Wellcome	inj	80 -40mg	160	\$13.64	14
TMP-SMZ		\$68.20	10	160	\$13.64	14
<u>Price differential:</u>						
9.2 to 1						
<u>New Ocular disorder therapy (e.g., vernal conjunctivitis)</u>						
Alomide	Alcon	op soln	0.1%	1	\$33.75	12
lodoxamide tr.		\$33.75	1	1	\$33.75	12
<u>Compared to:</u>						
Econopred	Alcon	op soln	1%	1	\$21.00	12
prednisolone acet.		\$21.00	1	1	\$21.00	12
Ak-Pred	Elkins-Sinn	op soln	1%	1	\$5.69	12
prednisolone phos.		\$5.69	1	1	\$5.69	12
<u>Price differential:</u>						
1.6 to 1 and 5.9 to 1						

\* Cost as of 12/31/93 expressed as \$ at average wholesale price (AWP).

Figure 5

## Cost of 1993 New Drugs versus Comparison Drug

Therapeutic Use				Daily Dose	\$/Day	Duration (days)	\$/Course
Brand/ Generic	Company/ Date Appr.	Dose Form/ AWP/pkg	Strength/ Pkg Size	Typical/ Max.	Typical/ Max.	Typical/ Max.	Typical/ Max.
<u>New Influenza A virus prophylaxis</u>							
Flumadine	Forest	tab	100 mg	200	\$2.37	7	\$16.61
rimantidine HCl	9/17/93 - 1P	\$118.67	100	200	\$2.37	7	\$16.61
<u>Compared to:</u>							
Symmetrel	Dupont M-S	cap	100 mg	200	\$1.64	7	\$11.46
amantadine		\$81.84	100	200	\$1.64	7	\$11.46
Price differential:		1.5 to 1					
<u>New Seasonal allergic rhinitis therapy</u>							
Claritin	Schering	tab	10 mg	10	\$1.77	30	\$53.17
loratidine	4/12/93 - 1S	\$177.23	100	10	\$1.77	30	\$53.17
<u>Compared to:</u>							
Seldane	M M Dow	tab	60 mg	120	\$1.77	30	\$53.17
terfenadine		\$88.62	100	120	\$1.77	30	\$53.17
Hismanal	Janssen	tab	10 mg	10	\$1.69	30	\$50.63
astemizole		\$168.76	100	10	\$1.69	30	\$50.63
Price differential:		1 to 1					

\* Cost as of 12/31/93 expressed as \$ at average wholesale price (AWP).

Figure 6

**Cost of 1993 New Drugs versus Comparison Drug  
Antipsychotic Therapy**

<u>Therapeutic Use</u>				<u>Daily Dose</u>	<u>\$/Day</u>	<u>Duration</u>	<u>\$/Course</u>
<u>Brand/ Generic</u>	<u>Company/ Date Appr.</u>	<u>Dose Form/ AWP/pkg</u>	<u>Strength/ Pkg Size</u>	<u>Typical/ Max.</u>	<u>Typical/ Max.</u>	<u>(days) Typical/ Max.</u>	<u>Typical/ Max.</u>
<u>New Antipsychotic therapy</u>							
Risperdal	Janssen	tab	4 mg	4	\$5.26	365	\$1,918
risperdone	12/29/93 - 1P	\$525.60	100	4	\$5.26	365	\$1,918
<u>Compared to:</u>							
Haldol	McNeil	tab	5 mg	10	\$2.62	365	\$958
haloperidol		\$131.17	100	10	\$2.62	365	\$958
(generic)	Par	tab	5 mg	10	\$0.65	365	\$237
haloperidol		\$32.50	100	10	\$0.65	365	\$237
Clozaril	Sandoz	tab	100 mg	300	\$10.26	365	\$3,745
clozapine		\$342.00	100	300	\$10.26	365	\$3,745

Price differential: 2 to 1 or 8 to 1 or 0.5 to 1

\* Cost as of 12/31/93 expressed as \$ at average wholesale price (AWP).



Figure 7

**Cost of 1993 New Drugs versus Comparison Drug  
Antiepileptic Therapy**

<u>Therapeutic Use</u>				<u>Daily Dose</u>	<u>\$/Day</u>	<u>Duration</u>	<u>\$/Course</u>
<u>Brand/ Generic</u>	<u>Company/ Date Appl.</u>	<u>Dose Form/</u> <u>AWP/pkg</u>	<u>Strength/ Pkg Size</u>	<u>Typical/ Max.</u>	<u>Typical/ Max.</u>	<u>(days)</u> <u>Typical/ Max.</u>	<u>Typical/ Max.</u>
<u>New Antiepileptic therapy</u>							
Felbatol	Carter-Wallace	tab	400 mg	2400	\$3.46	365	\$1,261
felbamate	7/29/93 - 1P	\$57.60	100	3600	\$5.18	365	\$1,892
Felbatol	Carter-Wallace	tab	600 mg	2400	\$2.64	365	\$964
felbamate	7/29/93 - 1P	\$66.00	100	3600	\$3.96	365	\$1,445
Neurontin	Parke-Davis	tab	300 mg	900	\$2.25	365	\$821
gabapentin	12/30/93 - 1P	\$75.00	100	1800	\$4.50	365	\$1,643
Neurontin	Parke-Davis	tab	400 mg	900	\$2.03	365	\$739
gabapentin	12/30/93 - 1P	\$90.00	100	1800	\$4.05	365	\$1,478
<u>Compared to:</u>							
Dilantin	Parke-Davis	cap	100 mg	300	\$0.54	365	\$198
phenytoin		\$18.07	100	300	\$0.54	365	\$198
(generic)	Harber	cap	100 mg	300	\$0.11	365	\$39
phenytoin		\$36.00	1000	300	\$0.11	365	\$39
Tegretol	Basel	tab	200 mg	400	\$0.69	365	\$253
carbamazepine		\$34.66	100	600	\$1.04	365	\$380
(generic)	Qualitest	tab	200 mg	400	\$0.23	365	\$83
carbamazepine		\$56.70	500	600	\$0.34	365	\$124

*Felbatol Price differential: 10 to 1 or 48 to 1 or 5 to 1 or 15 to 1*

*Neurontin Price differential: 8 to 1 or 42 to 1 or 4 to 1 or 13 to 1*

\* Cost as of 12/31/93 expressed as \$ at average wholesale price (AWP).

Figure 8

**Cost of 1993 New Drugs versus Comparison Drug  
Anti-arthritis Therapy**

<u>Therapeutic Use</u>		<u>Dose Form/ Strength/</u>		<u>Daily Dose</u>	<u>\$/Day</u>	<u>Duration</u>	<u>\$/Course</u>
<u>Brand/ Generic</u>	<u>Company/ Date Appr.</u>	<u>AWP/pkg</u>	<u>Pkg Size</u>	<u>Typical/ Max.</u>	<u>Typical/ Max.</u>	<u>(days) Typical/ Max.</u>	<u>Typical/ Max.</u>
<u>New Anti-arthritis therapy</u>							
Cataflam	Geigy	tab	50 mg	300	\$7.80	365	\$2,847
diclofenac pot.	11/24/93 - 3S	\$130.00	100	300	\$7.80	365	\$2,847
<u>Compared to:</u>							
Voltaren	Geigy	tab	50 mg	300	\$5.47	365	\$1,996
diclofenac sod.		\$91.14	100	300	\$5.47	365	\$1,996
Ansiad	Upjohn	tab	50 mg	300	\$4.38	365	\$1,597
furbiprofen		\$72.93	100	300	\$4.38	365	\$1,597
Nalfon	Dista	cap	300 mg	900	\$1.16	365	\$424
fenpropfen		\$38.76	100	1200	\$1.55	365	\$566
(generic)	Warner Chilco	cap	300 mg	900	\$0.93	365	\$340
fenpropfen		\$31.04	100	1200	\$1.24	365	\$453
Motrin	Upjohn	tab	400 mg	1600	\$0.79	365	\$290
ibuprofen		\$19.83	100	3200	\$1.59	365	\$579
(generic)	Halsey	tab	400 mg	1600	\$0.38	365	\$137
ibuprofen		\$9.40	100	3200	\$0.75	365	\$274
Feldene	Pfizer	cap	20 mg	20	\$2.47	365	\$903
piroxicam		\$247.35	100	20	\$2.47	365	\$903
(generic)	Roxane	cap	20 mg	20	\$1.30	365	\$475
piroxicam		\$130.00	100	20	\$1.30	365	\$475
Naprosyn	Syntex	tab	500 mg	1000	\$2.34	365	\$854
naproxen		\$117.01	100	1000	\$2.34	365	\$854
(generic)	Geneva	tab	500 mg	1000	\$2.08	365	\$760
naproxen		\$104.14	100	1000	\$2.08	365	\$760

*Cataflam price differential: 1.4 to 1 or 1.8 to 1 or 7 to 1 or 8 to 1 10 to 1  
21 to 1 or 3 to 1 or 6 to 1 or 3 to 1 or 4 to 1*

\* Cost as of 12/31/93 expressed as \$ at average wholesale price (AWP).

Mr. WAXMAN. Thank you very much, Mr. Schondelmeyer. Just to pick up on that point, you describe all these other countries with price controls or profit controls in their systems. Hasn't that meant that some of the consumers in those countries are going without drugs that they might otherwise need?

Mr. SCHONDELMEYER. All of the consumers in those countries within the health plan have access to the same level of drugs. I would point out that consumers who want to purchase drugs beyond what the health plan covers are free to purchase them on their own in the free, competitive market, the one we talk about here, but nobody seems to do that over there; nobody seems to do that very much in the European market, to use the private free market that we talk about here. If we established a Medicare program, anybody who wanted a drug that wasn't covered under Medicare would be free to go out and buy it on their own just like they are today.

Mr. WAXMAN. That might be easier said than done if you need a drug that costs \$10,000, \$20,000 or \$30,000.

Mr. SCHONDELMEYER. I agree. I think there are cost factors both in Europe as well as in the United States that prohibit patients from having access to pharmaceuticals.

Mr. WAXMAN. If other countries limit the amount that their consumers are going to have to pay for drugs, doesn't that just mean the American consumers are paying more in order to cross-subsidize them?

Mr. SCHONDELMEYER. We do pay a higher price in the United States for most products on the marketplace today. Economists will argue about whether that is cross-subsidy or the technicalities, but yes, we pay a higher price, and I think as the rest of the world is freezing or decreasing prices, we are only going to feel our prices going up faster. Even though I have empathy with the problem that drug companies have with the rest of the world squeezing, we can't ignore it and say, What problem? I don't see a problem.

Mr. WAXMAN. Do you think it would drive research-based companies out of the United States if we adopted some ways to limit the prices to our consumers?

Mr. SCHONDELMEYER. Again, you will get arguments in multiple directions, but my argument would be if we don't squeeze any harder than what Europe is already doing, then why would companies leave and go there? If we only give equal pressure compared to what other countries in the world are doing, it shouldn't have a differential effect on whether companies decide to stay in the U.S. market versus other markets.

Mr. WAXMAN. It seems like what we are trying to do in the Clinton proposal is not set price controls, although the companies told us they fear that that may result from a committee that could look at the reasonableness of their prices. We are not looking at price controls; we are looking at in the private sector some kind of formularies through managed care that would negotiate with the companies to choose one drug as opposed to another if they are similar based on price, and that leaves Medicare with paying the price that the manufacturers want unless there is some kind of mechanism that is set up for Medicare to do the exact same thing.



Is the result of that going to be to keep our drug companies from having the money they want and need to do the advances for the future?

Mr. SCHONDELMEYER. I think most people want more than they can get in the market. I hear drug companies complain that they fear price controls. Nearly every other provider in the health care system has had and continues to have price controls. I think this allegation or this statement "why pick on us?" is a bit hollow when everybody else has been picked on and this is one of the few groups that hasn't.

I'm not saying price controls are the answer *carte blanche*, but neither is a *carte blanche* blank check attitude toward the pharmaceutical industry in the best interest of our economy either.

Mr. WAXMAN. Let me just get a yes or no answer. Do you think that the President's proposal imposes price controls?

Mr. SCHONDELMEYER. I do not think it imposes price controls, no.

Mr. WAXMAN. Second, do you think that the President's plan would impair innovation for prescription drugs?

Mr. SCHONDELMEYER. No more so than the managed care competitive market would. If they are arguing that managed care can negotiate better discounts than we can get under a Medicare rebate, then how can they argue that the lower prices that managed care will be paying drug companies will hurt any more than the rebate Medicare would be getting? If the discount is even greater in the "competitive market," how come they aren't hurt more there?

Mr. WAXMAN. Mr. Love, you made a comment that I found interesting. You said drugs developed where public funds were used were higher priced than drugs that were developed with private funds being used. Why is that? How can you explain that?

Mr. LOVE. We don't know for sure why that is. That was a finding that we were surprised at when we saw it. I think what we believe is that drugs that were developed with public funds were better drugs and also that they were for more severe illnesses.

Mr. WAXMAN. These new breakthrough drugs that are so expensive, are you including some of those in the category of drugs developed with public funds?

Mr. LOVE. I think that the 30 drugs which are in this category would be the kind of drugs that people talk about as breakthrough drugs. They are drugs with a high FDA rating for efficacy and a rating for treatment of severe illnesses. So they are the kind of drugs that you talk about when you speak of breakthrough drugs.

I think that the government directs its resources in terms of its R&D budget toward the most important and severe problems in health care.

I would like to say that one of the issues I think in R&D is, what kind of bang for the buck do you get in terms of incentives to the company to do research? You take a drug like Taxol where the government not only invented the drug itself and took it all the way through phase III trials and sponsored and paid for all the phase III trials except for some of the manufacturing of the drug, which was done by Bristol-Myers in the last 2 years, but they also developed the manufacturing process and everything. You take a drug like that, you hand it over to a drug company where their predicted revenues are \$800 million a year off the drug, manufacturing costs



were about 6 or 7 percent of that, that's a big bonus, kind of, to the company.

It's not necessarily obvious that that is the most efficient way to provide incentives for the companies to do research. You want to give the companies profits from their own investments, not from the public's investments on the drug.

Mr. WAXMAN. But you do want the companies to take the public investments and use them wisely so that they will get these breakthroughs.

Mr. LOVE. Absolutely. I think Merck earlier today mischaracterized the government's investments as just basic research. About 24 percent of the clinical trials in the most recent year for which we had data were paid for by the government, which is a fairly advanced stage of research. It's not just basic research.

Mr. WAXMAN. I have to move on to let one of my colleagues have their chance to ask questions. Maybe we will get into some of these other areas.

Mr. McMillan.

Mr. McMILLAN. I assume everyone has read most of the bill.

Mr. LOVE. I read the sections on the breakthrough drugs.

Mr. McMILLAN. Is there any question in anyone's mind as to whether or not there is price setting in this bill?

Speak up. We don't record nods.

Mr. SCHONDELMEYER. It depends on how you frame that. I think the government reserves the right to make a competitive judgment in the marketplace to say "I don't feel that product is worth the price being charged." That's the same judgment that an individual consumer can make, the same judgment that an HMO can make, and I don't see any reason to prohibit our government from making price conscious, consumer-oriented, market-drive choices just like the private market does. Government can refuse to pay for certain products if they don't feel the price-value relationship is appropriate. I don't call that price setting; I call that exercising marketplace behavior as a government, and I hope my government does that.

Mr. LOTT. I think these are quite different than any normal market-driven type setting of prices. I can just read one thing from page 131 in the President's bill. It says, "Each regional alliance shall establish a fee schedule setting forth the payment rates applicable to services furnished during the year to individuals enrolled in fee for service plans."

I don't care what you want to call that. That is price controls, and it's quite a bit different than any type of normal market setting mechanism, because if I have managed care, which is something that Mr. Schondelmeyer had been referring to earlier, and I'm offered a certain price and I don't want to provide my service at that price, I can go to somebody else. In this case, if I don't provide my service at the price that the government sets, I go to jail. That is quite a bit different than a type of normal market setting arrangement which I think you are referring to.

Mr. SCHONDELMEYER. If I could comment. I interpreted your question to be in the context of prescription drugs. I don't see that statement that you read to have anything to do with prescription drugs.

Mr. LOTT. They talk about the reasonableness and other things.

Mr. SCHONDELMEYER. Does that statement refer to prescription drugs?

Mr. LOTT. Your general statement was about everything, I thought.

Mr. SCHONDELMEYER. No. I was talking about the Secretary's authority to refuse to pay for drugs that the Secretary didn't feel had an appropriate price-value relationship.

Mr. GRABOWSKI. Let me comment on that. I think there is a huge difference between a formulary done at a level of a managed care organization where you have a P&T committee that looks at value, that looks at cost, versus a government organization that is responsible for budgetary cost containment. I have studied the way Medicare has been administered in terms of formularies, and what you often get is formularies' decisions in which the beneficiaries don't get the latest drugs; they don't get the drugs on a timely basis that the FDA rates as 1-A; you get very much of a budgetary-driven, and that decision is being made at a very aggregate level. Now we are talking about making it at the whole level of Medicare.

I think there is a huge difference between formulary managed care at a decentralized competitive level and having it made by a single organization for the whole Medicare program involving a third of pharmaceuticals consumed.

Mr. GREEN. May I just add to that supplementary comments to support that argument. You've got to remember that high prices have a useful value in attracting investment and signaling where it is worthwhile for investors to put their money. Just take the example of the anti-ulcer drugs. Tagamet was the first one. It came out at quite a high price. It was quite successful. Then along came Zantac, which charges slightly higher price on the basis that it was slightly safer and had fewer side effects. Those have both been very lucrative products. Now there is a whole generation of anti-ulcer products called proton pump inhibitors which have been attracted into the marketplace, which are safer still, many would argue, although it remains to be seen since they haven't been on the market that long, which have been attracted by the high prices.

If you don't allow the high prices, you won't get the investment signals, you won't get the innovation, you won't get the creativity, and if you allow the government to try to even out the prices because it doesn't seem quite right at the time or it doesn't fit with the budget or it doesn't fit with its other priorities, then you will suppress—you may not altogether obliterate—you'll suppress the innovative market mechanism.

Mr. McMILLAN. What you are saying is that by withholding approval of the reimbursement for a certain pharmaceutical the way the law is written, the Secretary might win that battle and thereby force the price down on that one product, but it's the long-term effect on all products, all innovation more so than it is the effect upon that in that one instance.

Mr. GREEN. Because different prices send signals about where it's worthwhile to invest, yes.

Mr. WAXMAN. Thank you, Mr. McMillan.

Mr. Bliley.

Mr. BLILEY. Thank you, Mr. Chairman.

Dr. Green, at a hearing last week I showed a clip of a newscast from Canada showing how the hospitals in Canada were forced to shut down for all but emergency services for the last 3 weeks of the year due to their global budget. Has this ever happened in Great Britain?

Mr. GREEN. It has happened for many years and, if anything, it has gotten worse in recent years. The financial year in Britain ends at the end of March. Frequently in February and March hospitals stop taking all non-urgent admissions for surgery.

Mr. BLILEY. What happens to the hospital personnel? Do they get laid off?

Mr. GREEN. No.

Mr. BLILEY. Furloughed?

Mr. GREEN. No. They just carry on. There are always a certain number of emergency admissions.

Mr. BLILEY. Mr. Lott, if the Clinton bill is enacted and Congress later decides it has made a mistake with regard to price controls, what will it take to reverse the market for pharmaceuticals?

Mr. LOTT. I think it would be very difficult to reverse it and I think that's what makes this different than price controls we have had in many other areas in the past. I think it is going to be politically difficult, because I think you are going to have to go and tell people that they are going to have to put up with high prices again for a period of time before you'll begin to see new drugs beginning to appear. There is a large regulatory lag, for instance, along with development lag that has to occur. Whether or not you are going to be able to convince people to put up with those high prices for a while is questionable.

Also, you are going to be destroying the research organizations that exist. Those are very delicate things and hard things to put together, and whether they are going to be in place 8, 9, 10 years from now is going to be questionable.

And there are other problems that you have existing. Once you have been held up with price controls, the question is going to be, how do you know that the next time your new drugs start to hit the market again that they are not going to impose price controls on you again at that point? The very threat of that happening again in the future is going to discourage them even when you remove the price controls from beginning to see new drugs start to appear in the pipeline.

Mr. BLILEY. Thank you.

Mr. LOVE. The picture that is being described of the health care plan bill by Mr. Lott doesn't really describe the bill itself. There is some negotiation on some of the Medicaid and Medicare, but companies can charge whatever they want.

Mr. BLILEY. Not if they want to get approved for Medicare patients.

Mr. LOVE. I think that is one of the failures of the bill, because it puts the Secretary in such a bad position of either saying none of these patients get the drug or everyone gets it. I think that is one of the reasons why you ought to put price controls in the bill. I think that is what is wrong with the bill. It doesn't have price control and I think it's politically untenable to deny people the treatment. I think that is going to be the problem.



The history in the United States has been an excessive pressure on the drug companies. Nobody even asked them for information on what their prices are.

Mr. BLILEY. That is very interesting. You think that by putting price controls in the bill that it won't have any effect on research?

Mr. LOVE. I believe that everything that's in the bill will have an effect on research. I think that the mandatory coverage will have an effect and I think price controls and how you administer the price controls, if they existed, would have an effect. I think if it were punitive and you tried to strip the companies down to a rate of return based on their direct expenses, it would be a disaster. I don't think there is anyone that wants to do that. I think it would be unfair to characterize the attempt to have a review of breakthrough drug prices as that kind of regulation since there are really no proponents of that kind of regulation.

Mr. BLILEY. Do you agree with that, Dr. Grabowski?

Mr. GRABOWSKI. This would be a very difficult industry to impose public utility type cost controls. It's difficult enough where we have a homogeneous commodity like electricity and we are moving away from price controls of a cost type in that area.

When you are talking about R&D that occurs over long periods, where there are a lot of dry holes, where some firms win the lottery and other firms don't, to try to sort of set price controls based on costs in that environment, I think it's inevitable that there would be a lot of disincentives for R&D.

I agree that what would be hurt most would be the long-term risky type research, research that you are starting down a road that might be 10 or 12 years in the future where you have a low probability of success, but if you are successful, you hope for a premium return. Ex post the regulator can say, well, you've made that discovery and we'll give you something for research, but we're not going to give you sort of an extra thing because you did something risky; we don't think it looks that risky now versus 12 years ago.

I think that is the problem.

Mr. BLILEY. Thank you very much.

Mr. WAXMAN. Thank you, Mr. Bliley.

Mr. Greenwood.

Mr. GREENWOOD. Thank you, Mr. Chairman.

I would like to address some questions to Mr. Green. I want to compliment you on the statement in the preliminary pages of your testimony where you say "objectives of health policy sometimes become detached from or even inconsistent with the guiding principles fundamental to a free society." I think that notion is at the core of all of this discussion and debate we are having. I think it's pretty much agreed that we could reach the end of universal coverage if we are not concerned about what means we use to get there, but means matter and means have consequences other than the goal that they are intended to achieve.

I'm not sure whether you made much reference to this in your oral testimony, but there was a recommendation made at the end of your written testimony as a scheme for Britain that involved catastrophic insurance. Could you elaborate on the elements that recommendation?



Mr. GREEN. This was another way of coping with the problem that the administration is trying to confront with its proposal for Medicare. That is, some people don't have enough money to pay for any drugs and some people have enough money to pay for drugs most of the time, but when they get really sick, they are not going to be able to afford to pay for the really costly medicines.

What we proposed was that the poorest people should be given what we call a Medicaid, which would entitle them to free drugs, and that everybody else would have the option of paying for what would amount to catastrophe insurance coverage, which is another way of describing insurance with a high front-end deductible. So you would pay out of pocket for a certain amount and then you'd be covered beyond that.

We felt that would take care of most people, would take care of people who were poor in the sense of being indigent and people who couldn't afford to pay more than a certain amount if they got really very, very ill. And it would not have the same consequences of a price control regime and it wouldn't have a rationing effect.

Mr. GREENWOOD. How was your recommendation received?

Mr. GREEN. It was initially received quite favorably by one or two cabinet ministers, but then there was a bit of a public row and people began to argue that they didn't want to pay anything; they would rather have everything free. That's where it stands at the moment.

Mr. GREENWOOD. Which brings us to the issue of public opinion. You made some reference in your testimony to the fact that public opinion in Britain is moving steadily towards acceptance of a system based on personal and family responsibility rather than paternalism. Is that across the board with regard to Britain's health care system, or are we simply talking about the pharmaceutical aspects of it?

Mr. GREEN. I was thinking more of the pharmaceutical side of the National Health Service. I do think there is a growing willingness to start paying something more for medicines. We've always had a small prescription charge which involves payment for 20 percent of prescription items.

As to the system generally, it's very hard to get out of a system where people think they are getting something for nothing. That is a very powerful reason for not introducing this Medicare benefit in the way that it is currently envisaged, because if it turns out in the way that I think can be predicted from British experience, to lead to rationing and political dissatisfaction and demands for ever more spending, it will be very hard to get out of, and that is, I think, the main lesson from the British experience.

Mr. GREENWOOD. You commented earlier in response to another question with regard to the closing of hospitals periodically in Great Britain for all but emergency or essential services.

Mr. GREEN. It wasn't quite closing hospitals. It was not taking non-urgent admissions.

Mr. GREENWOOD. Has there been the same sort of experience with regard to the availability of medicines?

Mr. GREEN. It's very patchy. It varies a lot from place to place, but one can, by looking at newspapers and medical journals, put together a long list of denials of therapy. You can also measure by

looking at the rate at which Britain absorbs new medicines compared with other countries. For example, if you take new therapies introduced in the last 5 years, they comprise about 10 percent of British sales, whereas they comprise about 22 percent of American sales. So you can measure it in that way, the absorption of new medicines, and you can look at concrete cases, and I have cited several in the written testimony, of withholding of valued safe and effective therapies.

Mr. GREENWOOD. Thank you very much.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Greenwood.

Gentlemen, thank you very much for your contribution. You have given us a lot to think about.

That concludes our hearing. We stand adjourned.

[Whereupon at 5:30 p.m. the hearing was adjourned, to reconvene at the call of the Chair.]

[The following statements were submitted:]

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**Statement for the Record  
of the  
American Hospital Association  
before the  
Subcommittee on Health and the Environment  
of the  
Committee on Energy and Commerce  
of the  
U.S. House of Representatives  
on  
Health Care Reform and Prescription Drug Issues**

**Held on  
February 8, 1994**

The American Hospital Association (AHA) is pleased to have the opportunity to comment on the proposed addition of a prescription drug benefit to the Medicare program as a part of the Health Security Act.

Certainly AHA supports the concept of providing increased benefits, such as a drug benefit and a long-term care benefit, to the Medicare program, as is proposed in the President's health care reform plan. We cannot, however, support underpaying hospitals in order to pay for these benefits.

As you know, the Administration has proposed reducing future Medicare spending by \$118 billion, and using the savings resulting from these reductions to finance the proposed new Medicare benefits.

We believe this approach is based on deeply flawed public policy. The federal government, faced with steeply rising costs for the Medicare program, believes that such arbitrary, deep reductions in Medicare spending can slow these cost increases without harming the quality of patient care. This is, at best, a dubious and untested premise. The Administration's proposed Part A hospital spending reductions per Medicare enrollee would mean that hospitals would have \$1,265 fewer dollars per admission to care for Medicare patients in the year 2000 -- that's 12 percent less per Medicare admission in a single year. In 1991, overall Medicare payment already fell 12 percent short of meeting hospitals' costs for these patients. Today, hospitals make up these payment shortfalls by cost-shifting to privately insured patients. But under a reformed health care system organized around more tightly-budgeted managed care premiums, such cost-shifting would be precluded. We can all appreciate the implications for maintaining quality care to Medicare beneficiaries if the proposed reductions are put in place under those circumstances.

Hospitals agree that the growth in the nation's health care costs must be moderated -- including the rate of increase in the Medicare program. But the sound way to do that is to restructure our health care system to deliver more efficient and cost-effective care. And that means changing the financial incentives to reward more cost-effective preventive and primary care. It means moving more Americans, including Medicare beneficiaries, from traditional



fee-for-service arrangements with all their conflicting incentives into managed care arrangements in which providers are paid a fixed annual fee to care for an enrolled group of patients. The results can be impressive. For example, in our statement before this subcommittee last November 8, John King, Chief Executive Officer of Legacy Health System, Portland, Oregon, testified that Legacy saves patients between 5 and 30 percent of their historical health care costs. From fiscal year 1991 through fiscal year 1993, Legacy's cost per adjusted hospital admission rose only 4 percent. Legacy's cost containment effort, noted King, is driven by managed care, continuous quality improvement, administrative consolidation, and integration of clinical services.

In order to translate these savings into significant nationwide savings, however, reform must be broad-based. From the hospital standpoint, for example, an average 40 percent of revenues derive from Medicare patients. Imagine trying to run an efficient hospital if nearly half of what you do is driven by one set of financial incentives, and the other by entirely different -- in fact, exactly opposite -- incentives. Patients in the reformed health care system will have a financial incentive to purchase coverage from cost-effective providers. And those providers will have an incentive to use services wisely, because inappropriate use reduces the funds available for other purposes. Shouldn't Medicare beneficiaries also have strong incentives to seek cost-effective care and their providers have consistent incentives to treat them in the most cost-effective way?

There is a way out of this dilemma. And that is to encourage Medicare beneficiaries to choose the more cost-effective managed care arrangements upon which a reformed health care

system should be built. A number of managed care plans already have satisfied older members nearing retirement. If they were given an incentive to stay in such plans, they in all likelihood would do so. And current Medicare beneficiaries could be educated about the benefits of such plans, and then be given the opportunity -- and incentives -- to join them. There are a number of options that could serve as such incentives, including:

- make managed care arrangements less expensive than a fee-for-service option by waiving a current cost paid by Medicare beneficiaries -- deductibles, copayments, or a limit on patient days
- offer benefits in a managed care arrangement only that are currently excluded from Medicare coverage -- such as prescription drugs, long-term care, or more preventive services (i.e., not make these available to all Medicare beneficiaries)
- offer a point-of-service option in Medicare managed care arrangements. Today, providers who treat Medicare patients can be paid either on a fee-for-service or a capitated basis. This option would give enrollees a third choice: to "opt out" of the capitated payment arrangement, for a single episode of care, at any time to see a provider of their choice -- but at a higher cost to the beneficiary. This opens to Medicare beneficiaries the same care and payment options currently available to other Americans.

This is the larger context in which we would like the committee to debate the merits of adding a prescription drug benefit to the Medicare program. We are at a historic crossroads as we consider how to reshape our health care delivery system. The changes you and your congressional colleagues are considering must come together to work well as a whole -- no easy task when our health care system is so large and so complex.

Hospitals, however, believe the nub of reform must be the consistent restructuring of our health care delivery and financing systems into community-based managed care networks, paid on a capitated basis, that provide cost-effective and efficient care. And those networks should be available to all citizens, including Medicare beneficiaries.

## TESTIMONY OF

### AMERICAN SOCIETY OF HOSPITAL PHARMACISTS

(This statement on behalf of the American Society of Hospital Pharmacists (ASHP) is presented jointly by Paul W. Abramowitz, Pharm.D., and Joseph A. Oddis, Sc.D. Dr. Abramowitz is President of ASHP and Director of Pharmaceutical Services at the University of Minnesota Hospital and Clinic. Dr. Oddis is Executive Vice President of ASHP. ASHP appreciates the opportunity to present comments regarding certain aspects of President Clinton's Health Security Act. Please include this testimony as a part of the record of the Subcommittee's hearing held on February 8, 1994. )

ASHP is the 30,000-member national professional association that represents pharmacists who practice in health-care systems, including hospitals, health maintenance organizations, long-term-care facilities, and home-care agencies. The Society has extensive publishing and educational programs designed to help members improve pharmaceutical services. ASHP is a national accrediting organization for pharmacy residency and pharmacy technician training programs.

Our testimony will address the following issues: the outpatient drug benefit and pharmaceutical care, the "access to discounts" language, the breakthrough drugs committee, and the patient counseling provisions of President Clinton's Health Security Act.

The Society supports making an outpatient prescription drug benefit available to all Americans. Access to these pharmaceuticals is a necessary component for any health care reform proposal striving to control costs. Medications are used with great success to diagnose, prevent, and treat major acute and chronic illnesses and slow or halt the progression of more serious conditions. Although prescription drugs represent only seven to ten percent of the total health care dollar, when used properly their financial impact is far more significant.

It is on this issue of proper or appropriate use of prescription drugs that we join with our colleagues in other sectors of pharmacy in urging that Congress include as a core benefit pharmaceutical care or the services of pharmacists. Appropriately managed pharmaceutical therapy improves a patient's quality of life and lowers overall health care expenditures by reducing the need for costly hospitalizations, long-term care, and surgery. There are estimates that at least \$36 billion could be saved annually in the United States by improving patient compliance, reducing inappropriate drug use and related hospitalizations, and decreasing preventable adverse effects and interactions.

A pharmaceutical care benefit within a reformed health care system would acknowledge that patients have different needs for drug products and services. Pharmacists, in collaboration with physicians, patients and other qualified health care professionals, can work to manage and improve the appropriate use of pharmaceuticals. Within the next two weeks, ASHP and the other members of the Coalition for Consumer Access to Pharmaceutical Care will have pharmaceutical care legislation available for the subcommittee's consideration.



ASHP supports the "access to discounts" language in the President's proposal to the extent that it endorses the current behavior of the multitier drug pricing system. That is, a system that allows for the offering of discounts for volume; additional discounts for such economic inducements to the manufacturer as prompt payment, cash payment and single-site delivery, and deeper discounts that reflect the purchaser's ability to move market share through the use of the formulary system, therapeutic interchange, and other mechanisms.

We understand that pharmaceutical purchasers will continue to obtain discounts based on terms "effectively reducing the manufacturer's costs," according to the President's proposal. The difference is that manufacturers, under penalty of exclusion from participating in Medicare, may not deny comparable benefits to the community pharmacy sector when it presents the same economic advantages to the manufacturer as those presented by large institutional and group purchasers. According to information ASHP has received from the drafters of this provision, similar discounts would be provided the community setting in proportion to the extent of the "advantage" presented the manufacturer by the purchaser, and not merely by compliance with a checklist of advantages, irrespective of degree.

As we view it, granting the community pharmacy setting the statutory right to discounts when it meets these criteria \*does not impair the right of the institutional pharmacy setting to the same negotiated discounts earned in the past. Some pharmaceutical manufacturers, however, may initially resist any requirement that they document and justify the discounts they offer. Furthermore, to the extent that the "pool" of those eligible to receive these discounts becomes larger, there is the risk that the rate of discount may be temporarily altered as industry and the marketplace adjust to the real or perceived impact of the provision.

ASHP would have preferred the absence of statutory language on the subject of discounts, allowing normal market forces to have their effect. We are aware, however, that a previous proposal subsequently rejected by the White House would have limited discounts to volume only. Such language would have precluded institutional and group purchasers from obtaining deeper discounts due to their ability to move market share. From our perspective, the current language does not remove this advantage from the institutional setting. If it did, we would oppose it.

In an effort to provide increased consumer access to and coverage for affordable innovative pharmaceuticals, the Health Security Act proposes the establishment of an "Advisory Council on Breakthrough Drugs." Although the purpose of the Council is to improve patient outcomes through cost effective drug therapy, we believe the key functions proposed for the Council are best performed by elevating the role of local or regional pharmacy and therapeutics (P&T) committees, or similar entities, as a component of formulary systems. These have proven successful in improving the quality of medication use and controlling drug expenditures. They also preserve the integrity of the physician-pharmacist relationship in making medication use decisions in the best interests of the patient.

Therapeutic interchange has proven especially useful for enhancing the effectiveness of prescribed medications while controlling their costs. ASHP believes it could be used to address the concerns assigned to the President's Advisory Council on Breakthrough Drugs. We define the term as the interchange of various therapeutically equivalent drug products by pharmacists under arrangements between pharmacists and prescribers who have previously established and jointly agreed upon conditions for interchange. These agreements can vary between simple understandings to complex protocols. Typically the P&T committee acts on behalf of the medical staff of the institution to develop and approve these arrangements. We are aware, however, of the unique problem presented by costly breakthrough drugs for which there are as yet no therapeutic alternatives.

We are disappointed that the pharmacist counseling requirements found at paragraph eight of Sec. 2002 are a substantially diluted version of the language originally found in the September draft of the bill. There, the language provided that pharmacists participating in the Medicare DUR program were "required to offer counseling to Medicare customers on the use of medications." This mirrored the mandate established in the Medicaid counseling language found in OBRA '90. The current language in the Health Security Act only requires that a representative of the "pharmacy", not necessarily a pharmacist, must only offer counseling when it is initiated by the Medicare enrollee. This is an unacceptable step backward, and certainly one which is not in the best interest of the patient. We are actively working with congressional sponsors of the bill to retain, at a minimum, the pharmacist counseling standard already in place for Medicaid patients.

In conclusion, because of their expertise with outpatient drugs, pharmacists can facilitate the proper use of medications and compliance with a physician's therapy. Knowing the importance of the prescribed pharmaceutical, they can stimulate and guide a conversation on the appropriate use of a drug and, therefore, encourage and respond more effectively to questions.

We appreciate the opportunity to present our views on the above referenced aspects of the Health Security Act. We look forward to serving as a resource to Congress as it continues its consideration of this and other proposals.

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\*Our research, which we provided to the subcommittee's staff, revealed the existence of at least 65 group purchasing organizations for community pharmacies, some of which have developed their own formulary systems. Approximately 52% of community pharmacies secure discounts from manufacturers through such cooperative arrangements.



## NATIONAL ASSOCIATION FOR SICKLE CELL DISEASE INC.

STATEMENT OF LYNDA K. ANDERSON, EXECUTIVE DIRECTOR

SICKLE CELL DISEASE ASSOCIATION OF AMERICA

SUBMITTED TO THE

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

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The Sickle Cell Disease Association of America, Inc. (formerly the National Association For Sickle Disease, Inc.) was organized in 1971 in order to create national awareness of the problems centering around sickle cell conditions and to develop recommendations and programs for the resolution of those problems. As the first organization to conduct a full time national effort to identify and counsel carriers of an inherited condition, the Sickle Cell Disease Association of America has uncovered a number of legal, social and ethical issues leading to the development and implementation of guidelines that have become a model for other health agencies dealing with genetic conditions.

In addition, the Sickle Cell Disease Association of America has provided ongoing research support, public, patient and health care provider education, screening, genetic counseling, vocational rehabilitation and other services through its 75 member chapters nationwide so that individuals can live lives that to the extent possible are not compromised by sickle cell conditions.

Sickle cell disease is an inherited, chronic and severe blood disease where the red blood cells become sickle shaped. This abnormality results in their ability to obstruct the flow of blood. Also sickle shaped cells are fragile resulting in a reduction in their life span. The disease affects primarily African Americans. Ninety-nine percent of those who die from the disease in the United States are African-Americans. Of the nearly 13 percent of the U.S. population that is African American, 8 percent has the sickle cell trait. When both parents have sickle cell trait, there is a 1 in 4 chance in each pregnancy that their baby will have sickle cell anemia. One in approximately every 560 African-American infants is born with sickle cell anemia. Children with this disease are 400 to 500 times more likely to contract very serious infections, particularly pneumococcal sepsis that can result in sudden death. Sickle cell patients suffer frequent acute painful episodes that send them to hospitals and emergency rooms. The treatment they receive is palliative - there is no cure and no preventive for this disease.

What will health care reform mean to the nation's 50,000 sickle cell patients?

MEMBERS OF NAT'L VOLUNTARY HEALTH COUNCIL JOINED HEALTH APPEAL OF AMERICA  
NATIONAL HEADQUARTERS 3345 WILSON BOULEVARD SUITE 1105 LOS ANGELES, CA 90010-1880 TEL: 313-736-5455 800-421-8453 FAX 213-736-5211

Broadly, we believe that an important goal of healthcare reform should be to empower the patient to make choices that will enhance the likelihood of a positive health outcome. We believe that, by providing universal access to care, the Administration plan will further this goal. Health security, "health care that's always there," is extremely important to sickle cell patients.

Patients with chronic diseases must have health care without restrictions. It is the responsibility of health care reform to address and cover specialized treatment, pharmaceutical needs, outpatient care, frequent hospital visits without dollar restrictions. And patients, regardless of economic or employment status, must have access to the best, state-of-the-art treatment.

I mentioned earlier that there is no cure for sickle cell disease. Until recently, there was little hope of a cure. But there are currently five medicines in development to treat this disease. One, hydroxyurea, is in clinical trials. It is being used on sickle cell patients and the preliminary results are very encouraging. Acute episodes have been reduced, and pain controlled. That means fewer frantic trips to the emergency room for sickle cell patients, and more control over their lives.

This particular medicine is not a cure for sickle cell disease. Experience with other diseases has shown that cures rarely come with the first wave of medicines. First, scientists strive to control the symptoms of disease. Later, they progress to controlling the mechanism of disease. The final step is cure or prevention. We are hopeful that the medicine now in development will lead to a cure for sickle cell disease.

This process takes time, it takes research, and it takes money. The research conducted by pharmaceutical companies is of life-and-death importance to sickle cell patients, and we want to be sure that nothing in the health care reform plan will discourage investment in research. We are concerned that certain provisions in the plan, notably the "breakthrough drug committee" may scare investors away from drug research. This is already happening in the biotechnology industry, whose research could well lead to a cure for sickle cell disease -- if it continues.

We are confident that, once a cure is developed, we can persuade drug companies to supply it free or at low cost to those who need it but can't afford it. But if price controls or other discouraging measures prevent a cure from being developed, sickle cell patients will be the losers. And so will the health care system, which will have to absorb the cost of maintaining and treating sickle cell patients without curing them.

On behalf of the nation's sickle cell patients, the Sickle Cell Disease Association of America urges the Subcommittee to consider the importance of drug research and the impact that health care reform legislation may have on the development of a cure for this painful costly disease.





## **HEALTH CARE REFORM**

### **Health Equity and Access Reform**

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**THURSDAY, FEBRUARY 10, 1994**

HOUSE OF REPRESENTATIVES,  
COMMITTEE ON ENERGY AND COMMERCE,  
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT,  
*Washington, DC.*

The subcommittee met, pursuant to notice, at 3:34 p.m., in room 2123, Rayburn House Office Building, Hon. Henry Waxman (chairman) presiding.

Mr. WAXMAN. The subcommittee meeting will come to order.

This afternoon we are continuing our hearings on other health care reform bills. Our witness today is the principal sponsor of H.R. 3704, The Health Equity and Access Reform Today Act.

I'm pleased to welcome our colleague in the House from the great State of California, the Honorable Bill Thomas, who is also a member of the Ways and Means Committee.

Mr. Thomas, we welcome you to our hearing. Your prepared statement will be in the record in full, and we'd like to ask you to proceed, however you see fit, with your oral presentation.

#### **STATEMENT OF HON. WILLIAM M. THOMAS, A REPRESENTATIVE IN CONGRESS, FROM THE STATE OF CALIFORNIA**

Mr. THOMAS. Thank you, Mr. Chairman. I do want to put the extensive written statement in the record.

And I want to tell you that we had planned to appear together with Senator Chafee, who is the principal sponsor of similar legislation on the Senate side. But we have just concluded the series of hearings in the Health Subcommittee of the Ways and Means, in which a number of senators were there earlier. Given the pressing demands of all of our time, he probably will not be able to make it, but I appreciate the time you have afforded me.

In outlining some of the concerns that I think are addressed in H.R. 3704, it is a bill that, unfortunately, has not been costed-out by the Congressional Budget Office in its entirety in the form in which it is currently before us.

Key portions of it, however, have been priced out by Joint Tax Committee and others as we are finding out that there are a number of pieces in a number of bills that are not new, novel, or unique. And we have put together a package, based upon certain premises that I would like to share with you, which led us to the conclusions that are contained in H.R. 3704.

Number one, we believe, the Senator and I, that the debate has reached a point in which universal coverage is a given. There may be debates as to how you reach it. And, clearly, after the CBO testimony in front of your committee as well as ours, the President is reevaluating when and how he reaches his universal coverage; that is, stretching it out, we examined our provision, and we provide for universal coverage.

We do it differently than the President does. We use an individual mandate. The reason for that, primarily, is that if we use the President's plan, it creates a \$10 to \$15 billion brand new bureaucracy in the Department of Labor, which, in essence, recreates the collection and delivery structure of the IRS and the Treasury Department. And we don't believe that there is a need to create another IRS in the Department of Labor.

It is a proven collection and dissemination mechanism, and the individual mandate then affords you a vehicle for providing universal coverage.

We provide the principle funding of the universal coverage through a reduction in the Medicare payments. Over a 10 period, from 1995 to 2005, we gradually reduce Medicare from its current 12 percent per year increase to a 7 percent per year increase.

I know there has been much criticism of the President's plan about a \$124 billion reduction over 5 years. That glide slope, I believe, is too steep and probably not realistic, and unachievable.

The 10 year reduction from 12 percent to 7 percent, I think, is imminently reasonable. Those savings are funded then into a voucher structure through the IRS system to buy-down, initially, completely 100 percent of the cost of premiums to those at 90 percent or below of the poverty level, sliding up to finally, in the final year, 240 percent of the poverty level.

In addition to that, we believe that there are cost containment mechanisms that are long overdue, that need to be changed. One of the principle ones in our bill is a tax cap.

Now, more than 10 years ago, I tried, with an amendment in the Ways and Means Committee, to put an outside limit on the fringe benefits in the tax code. We lost by two votes. Frankly, I think had we put that tax cap in 20 years ago, we would not have seen some of the runaway insurance costs, the routine behavior of third party payors, and the threshold and only question that consumers now ask, and that is, "Does my insurance cover it?"

There would have been a requirement to examine, under a reasonable cap, choice, and those choices inevitably lead to knowledge, and knowledge leads to an understanding of when and how payments are made. That has never been a requirement in our system, and we believe that a tax cap is a meaningful cost reduction mechanism.

In addition to that, Joint Tax told me in the last Congress that by placing a reasonable tax cap, the criteria I used in the last Congress was the low Blue Cross/Blue Shield plan, and what it entailed, which certainly is not magnificent, but it's a decent package.

But if, in fact, that were imposed over a 5 year period, 1993 to 1997, that would generate enough money, providing for a deduction up to the Blue Shield low option. That would provide enough

money to pay 100 percent of all the self-employed's deduction up to that level.

It would provide, in addition, enough money to pay for all of those who now pay for their insurance, who are employed by an employer who does not pay for their insurance, up to the deductible, with \$7.7 billion left over, which we would use as an initial funding of the voucher for the buy-down of the cost of the premium for below poverty level people.

In addition to that, Mr. Chairman, we contain I think what is now being called the usual suspects, in terms of the anti-trust reform, malpractice reform. Frankly, we have a package that we think is better than the President's package on malpractice—the small group insurance reforms, anti-trust reforms, administrative simplification for the collection of data which is essential to an informed consumer.

We believe you do not have to reinvent the system. But the rules under which the system has played over the last decade and more do need to be changed. We believe you can reach universal coverage, and that, in fact, you do not need to have a negative impact on the deficit, as the President's plan does. We do not. Ours is deficit neutral in the way in which it is funded.

And, a reasonable rules change, in the areas that I outlined, will continue the direction of the private sector with the changes on the State, toward reducing the costs of health care.

I do not believe that we can continue to labor under the concepts of the late 1980's, in terms of the cost increases. The medical price inflation factor, as reported by the Department of Labor, for 1990 was 9.7 percent. For 1991, it was 6.7 percent; for 1992, it's down to 6.4, and 1993 was 5.4 percent. The December monthly figure was 4.40 percent.

Frankly, I believe structural changes in the private sector and at the State level have helped bring about this downward direction of inflation. It's still higher than ordinary inflation. But we believe that the changes at the Federal level in this bill, reinforced with the tax cap, is more than sufficient to continue that kind of behavior.

In addition, I have one final item, Mr. Chairman.

We have purchasing cooperatives in our bill. We believe they're a relatively positive influence in the way in which people purchase health care—especially for small groups, who do not get the multiplication of size in administrative costs and other areas.

We do not mandate purchasing cooperatives. We believe that if, in fact, they are destined to be the model that most people will use, they ought to earn that position in the marketplace, rather than being imposed by government.

I thank the chairman.

[The prepared statement of Mr. Thomas follows:]



**Statement of the Honorable  
BILL THOMAS  
Member of Congress, 21st District of California**

**before the  
Committee on Energy and Commerce  
Subcommittee on Health and the Environment**

**February 10, 1994**

Mr. Chairman, thank you for this opportunity to address the Subcommittee today along with my good friend Senator Chafee. The President has challenged this Congress to pass a health care reform bill that will provide universal coverage to every American and slow the growth in health care costs. I am pleased to present to the Subcommittee the bill introduced by myself in the House, H.R. 3704, and introduced by Senator Chafee in the Senate, S. 1770, which would accomplish both of these goals over a reasonable period of time and in a rational manner.

The Chafee/Thomas bill requires that, beginning in the year 2005, every citizen of the United States must be covered, at least at the minimum benefit level, by a health insurance plan. In order to assist low-income individuals and families to meet this requirement, the bill provides vouchers to those with an income up to 240% of the poverty line, on a sliding scale based on ability to pay, with those at the poverty level receiving a 100% subsidy for the basic benefit package.

In addition to the individual mandate and the federal buy down for low-income individuals and families, the Chafee/Thomas bill includes several other crucially needed, and widely accepted, reforms to the health care system to ensure that every person in the United States has access to quality health care. The Chafee/Thomas bill would:

1. Prohibit insurance companies from excluding people with a preexisting condition from coverage and guarantee renewability of coverage.
2. Require all employers to provide information to their employees on basic benefit packages that are available in their health care area and deduct any premiums from their checks.
3. Encourage the development of voluntary purchasing cooperatives, of which there can be more than one, in the health care areas developed by the States.
4. Extend 100% deductibility of health insurance costs to both the self-employed and the individual who must pay all or part their own insurance premiums.

6. Give States flexibility to reform their Medicaid programs, allowing them to cover more people with the same or fewer dollars.
7. Develop and expand programs to increase the number of primary care physicians and improve access to quality health care services in underserved rural and urban areas.

The Chafee/Thomas bill will result in universal coverage, but the approach differs from the President's in two major aspects.

First, the Chafee/Thomas bill would not create a new federal bureaucracy to enforce another mandate on American business. Not only is an employer mandate an onerous requirement on low-wage companies, it is an inefficient way to provide assistance to those who currently do not have insurance.

As proposed by the President, the employer mandate would require a new structure be established in the Department of Labor to enforce the requirement on business. In addition, as this Subcommittee has heard from several economists, it is not the employer but the employee who ends up paying for the mandate through lower wages. This was echoed by the Congressional Budget Office in their report on the President's plan. Proponents of the Chafee/Thomas believe that it is more efficient, more cost-effective and more honest to require the employee to have insurance and then provide assistance directly to those who need it, instead of funneling that assistance through a smoke screen of employer regulations and subsidies to businesses.

Second, the Chafee/Thomas bill would attain universal coverage in a manner which ensures that the program will not add to the federal budget deficit. When the First Lady testified before the Ways and Means Committee last year, I asked her whether she would accept a provision which would require that the budget cuts in the President's plan be realized before additional benefits are provided. Her answer, in essence, was "NO." As we heard on Tuesday during the testimony of Dr. Reischauer on the Congressional Budget Office report on cost estimates of the President's plan, during the six-year period beginning fiscal year 1995, the plan will increase the deficit by \$70 billion, and that is assuming that Congress will have the political fortitude to enforce the strict premium caps and implement the Draconian cuts in Medicare and Medicaid. Health care reform must be fiscally responsible or it has the potential of bankrupting future generations.

The Chafee/Thomas proposal, on the other hand, is fiscally responsible. It would require that specified reductions in Medicare and Medicaid spending -- the reductions are far less than those proposed in the President's plan -- are realized before the vouchers are phased-in. It also includes a cap on the

deductibility of health insurance costs, which is set at a level which still provides consumer choice, to cover the cost of providing a 100% deduction to self-employed workers and individuals who must pay all or part of their health care premiums.

Aside from reducing federal tax expenditures, the tax cap also creates discipline within the health care system to reduce costs. Currently, with an unlimited amount of health insurance costs that can be deducted by the business and excluded from income by the employee, there is no incentive to prioritize health care needs and negotiate the best rate possible. A tax cap would force employees and employers to think more about what they want in their health care package and what they are willing to pay.

The Chafee/Thomas bill also includes several other provisions designed to reduce the growth of health care spending in the United States. Although the current downward trend in medical-care price increases is a positive sign and demonstrates that the strict cost control measures included in the President's plan are unnecessary, it does not mean that further cuts in wasteful spending are unnecessary.

First, the Chafee/Thomas bill would eliminate excessive regulations and unnecessary paperwork, which greatly increase the cost of providing health care in the current system. The bill would standardize claim forms, preempt state laws which hinder the electronic transmission of claims and other records and provide consumers with information on the comparative value of medical services. Each of these provisions would streamline the provision of care in the United States, thus saving providers and consumers millions of dollars every year.

Second, the Chafee/Thomas bill would provide an exemption from antitrust laws to providers who enter into a joint venture to increase efficiencies, expand access, reduce costs and eliminate excess capacity, or share high technology equipment or medical services. Such an exemption, which is more expansive than that included in the President's plan, would enable providers to coordinate efforts to provide the highest quality of care in the most cost-effective manner to all areas of the United States.

Third, the Chafee/Thomas bill would discourage frivolous malpractice claims, limit malpractice awards and eliminate the need for defensive medicine, all of which add unnecessarily to the cost of health care in the United States. This is achieved by requiring the use of an alternative dispute resolution system, capping noneconomic damages, limiting contingency fees, limiting liability to participation in the harmful act and directing punitive damages to the State for the purpose of reducing medical malpractice. Once again, these reforms go beyond those proposed by the President but they go to the heart of the problem and are long overdue.

Fourth, fraud continues to be a growing problem in our health care system. Billions of dollars each year are fraudulently billed to insurance companies and taken from consumers. Current law is not adequate to prevent fraudulent activity.

The Chafee/Thomas bill would enhance the Federal Bureau of Investigation and the Inspector General's office at the Department of Health and Human Services to detect and investigate fraud and the bill protects whistleblowers. The bill also permits private insurers to deny reimbursement to providers who commit fraud, just as the government does, and allows for the forfeiture, after conviction, of property either involved in a health care fraud scheme or obtained with the proceeds of such a scheme. These reforms would greatly reduce health care fraud in the United States, and they can be passed today.

Finally, the Chafee/Thomas bill provides consumers with the option of opening a medical savings account, known as a MediSave account. These accounts would allow consumers to make the health care spending choices they and their doctor believe are most cost-effective. They also reward consumers who use health care dollars prudently by allowing them to rollover any leftover funds in the account to the next year.

The most crucial element to controlling costs in the health care system is to get the consumer more involved. In this assertion we are in firm opposition to the single payer advocates who want access to the tax base to provide care to all with little or no discipline to use the health care system prudently. The current threshold question of "Will my insurance cover the procedure?" must be replaced by informed dialogue between the patient and their doctor about the efficacy and cost of the procedure. MediSave accounts, as well as the cap on the deductibility and excludibility of health insurance premiums, will force consumers to be more informed and participatory in their health care decisions, thus reducing health care costs.

The access and cost control provisions in the Chafee/Thomas bill are designed to address the problems currently found in our health care system, not the ones found in the health care system of the late-1980s. These reforms can be accomplished now, bringing much-needed relief to American consumers, and I urge the Subcommittee to pass this legislation and send it to the President for his signature.



Mr. WAXMAN. I thank you very much, Mr. Thomas, for your presentation to us.

Under your bill, as I understand it, all Americans not eligible for Medicare or Medicaid or other Federal programs, would be required to purchase coverage through a qualified health plan. A qualified plan, in turn, is required to offer one or both of the following benefit packages: a standard package and a catastrophic package. Thus, a plan could afford just the catastrophic package, and an individual could meet the coverage mandated by selecting just the catastrophic package.

Both the standard and catastrophic packages are generally outlined by the legislation. But most of the important details, including the level of cost sharing, are to be filled in by a national benefits commission.

Why did you decide not to specify a minimum benefits package, including co-insurance deductibles, and other out-of-pocket expenses, and how will the American people know what they're getting?

Mr. THOMAS. This is part of the maturation and education process, along the route to health care reform. And I'm still open to that discussion.

I started off with a specific dollar amount, and it was fairly obvious from the beginning that if you used dollar amounts, there were all kinds of ways to create adverse selection. And, frankly, the industry would be more clever than we would in coming up with packages that would continue to "cherry pick".

However, the opposite position of a very, very specific mandated package in front of Congress and voted on, I think, has just as great a potential for an onerous outcome; and that is, that the benefit package of all Americans becomes a political football, and that people run for office with the promise that they are going to advocate and, in fact, put into the basic benefits package particular items.

I am not sanguine about sitting as the Health Subcommittee of Ways and Means, and having 50 people lined up outside my office, believing that the health benefits package is very, very good, but it would be perfect if you would just add this one additional benefit. That kind of political pressure, I think, we probably, as an institution, would not be able to resist.

And so what we have in the bill is a generally defined benefit package. Their areas are clear, specific parameters. And the way in which the words are used and usually defined in the medical community clearly indicates parameters beyond which you can not go.

But the job of the specificity of the structure probably, at this stage of my education, I would be willing to leave to a group to put together, and then the final vote on Congress on accepting or rejecting.

If you have a better mechanism which does not put us in the position of utilizing the benefits package as a narrow political football, I'm open to any kind of a change, which would lead to a reasonable structure for including and modifying the benefits package.

Mr. WAXMAN. As I understand it, your bill contains a tax cap; that is, workers would pay income tax on their employer's pay-

ments for their health insurance premiums, if those payments exceeded the average premium cost of the lowest price standard benefits package in the area.

I take it you believe that this will deter employers from offering broad coverage to their employees, and will deter employees from demanding such coverage. To play out the theory, if Americans have less coverage, then health care costs will go down, because consumers will be more cost conscious.

Under your bill, how much more in personal income taxes would those Americans with good employer-based coverage today have to pay in order to continue that coverage? Or, let me put it another way. What do you estimate to be the amount of money this provision would take out of the pockets of the currently insured, and deposit in the U.S. Treasury?

Mr. THOMAS. I appreciate the way you put the question, Mr. Chairman. And I started off by saying that the Congressional Budget Office has not costed-out our bill, and we have not been able to obtain those numbers. However, the analysis that you just gave me is one that I think we should spend a minute analyzing.

Ten years ago, 20 years ago, to the present time, inflation excepted—that is, take inflation out—total compensation to workers has increased 12 percent. Wages in that same 20 year period have decreased 6 percent.

Clearly, there was a decision made, either in the collective bargaining system through unions, or between the negotiations between employers and employees, to utilize fringe benefits over wages. I believe that was prompted by the failure to have a tax cap.

If, in fact, we place a tax cap in place, there is nothing automatic or for sure about the fact that there would be a significant jump in the costs or in the presence of the health care package as either up or down. One of the things that I think you are going to see is a drive towards wages rather than fringe benefits. I think that's positive. I don't think it's negative.

I think you are going to have—and I speak from personal experience in the 1970's, when I negotiated benefits packages for teachers and classified in a very large, multi-campus school district. We would sit around, trying to dream up what we could place in the fringe benefits package, because of the way in which it was paid.

Frankly, we were very clever about it, if I might say so. We wound up with an 8 percent tax sheltered annuity cash out of the fringe benefits area. Of course, when I came back here, we have since modified the law to say that you can't cash out the cafeteria plan. But it was available under the law at that time.

People should quit spending their creative energies trying to figure out how under these rules they can beat the system. If you put a reasonable tax cap in, over time, what might be above the line in fringe benefits might wind up on the negotiating table on which they don't want that second back-up on the dental, and that instead, pull it off of there, and move it over to wages. I have full confidence in the unions to be able, over time, to make adjustments with the employers in that area.

Second, a number of these packages are out there, and the employers, simply because of a competitive model in looking for em-

ployees cannot make the kind of drastic changes that you are talking about. I believe there will be a reasonable adjustment period.

But what we're offering, and that's why we don't use the lowest cost plan in an area as the criteria, I believe that's too draconian, and it leaves no ability to have flexibility in the system. We do want to point in the direction that we should go, and that is, the average of the lowest half, so that you have some movement within that structure.

But, once again, I am more than willing to sit down and talk about a mechanism, if there is a downside, and I can be convinced that there is a horrendous downside, to take the currently negotiated packages, under the old rules of open-ended fringe benefits write-off, and within a 5 year window or a longer period, make sure that the total compensation package to employees is not diminished, using these tax cap as the device to have Americans lose health insurance.

There are a number of items that I've looked at to try and guarantee that. I have not put it in the bill, because I'm not satisfied with the mechanisms that I've seen. But that is not the intent of the legislation.

And if someone can show me that, in fact, there is a very likelihood that that would occur, there are provisions that can be put in to guarantee, on a grandfathering or a phase-out to that benefits package level.

Mr. WAXMAN. Thank you very much.

Mr. Greenwood?

Mr. GREENWOOD. Thank you, Mr. Chairman.

There's a lot of this legislation that I find very attractive, Bill. What I'd like to focus on is the voluntary purchasing cooperatives.

Would you lay out for us the differences between what small employers are able to do currently, like securing health care coverage through their Chambers of Commerce, and what new opportunities they would have under your proposal?

Mr. THOMAS. The thing you have to keep an eye on, Jim, is not just the purchasing cooperative, whether mandatory or voluntary, but in virtually all the plants, the general understanding of the changes that need to be made in the insurance industry itself.

Now, you've got the single payors, who say the insurance people shouldn't be involved in the equation, whatsoever, and we ought to eliminate them. I think we lose a real potential for creativity and a positive synergism in the system, if we remove them.

The problem is, we've let them, in essence, define the rules and play the rules the way they want to. The new rules will be, you cannot deny insurance to anyone. You cannot on the basis of pre-condition, deny.

One of the difficulties we've had is the ability of trying to community rate. We don't believe we have the tools to do that now, so we've left age in. And there are several items in there that, frankly, are a concession to reality, because I would rather be realistic than unrealistic in trying to make changes.

If we had a model that would clearly give us a pure community rating, I would plug that in. I haven't seen one. In fact, the CBO analysis in Chapter 5 says the President is clearly deficient in



some kind of a risk adjustment mechanism, and that's one of the downsides of his plan.

So in this new world of insurance companies requiring to offer insurance under the new rules, I think small businesses are at a disadvantage because of the simple numbers game. We don't think the purchasing cooperatives ought to have the exclusive mandate of the government for the pooling purpose.

I think insurance agents, dealing through Chambers of Commerce, Farm Bureaus, or other structures, might be able to come up with some new and novel plans that would give the purchasing cooperatives a run for their money; or at least require them to re-evaluate where they're coming from.

That's why we don't believe you should offer an exclusive purchasing cooperative in a given health care area. We have multiple purchasing cooperatives, so that, again, they keep each other honest.

I don't think we've written the last chapter on the structures for health care delivery. Had we done so by statute 20 years ago, you wouldn't even have managed care as an option, because it's come up, basically, in the last 20 years as a really positive concept. And, in fact, California is now virtually a managed care State.

Is it going to stay a managed care State? I can tell you how to guarantee it, and that's lock it into legislation. But I think that's the wrong thing to do.

So we believe they are very positive and useful models. But we ought not to mandate them by government; we make them voluntary. And, frankly, if they are going to win, they ought to win in the competitive marketplace.

Mr. GREENWOOD. With a voluntary purchasing cooperative, how do you escape the degenerating risky nature of the pool, where those who are in the voluntary cooperative are in there because they can't get a better price outside? It seems to me that the insurance companies would try to cream that pool by picking out the healthiest members. As a result, the risk pool degenerates until it becomes more expensive.

Mr. THOMAS. We're in the learning process in that regard, Jim. In California, we have voluntary purchasing cooperatives. There are requirements in which you must offer insurance. You can't deny the insurance. You can't "cherry pick" from a positive point of view about who gets the insurance. You can't deny insurance to individuals.

And although the voluntary purchasing cooperative only went into effect in July of last year, we are beginning to collect evidence about the real world versus the mythological world, and that we do not see, given the changed rules of the insurance game that we put in place, the kind of activity that you are concerned about.

Clearly, some insurers have left the State, because they did not want to participate, or did not think they could participate in that kind of a model. But I think they are beginning to realize that once they understand the new rules of the game, they are back in and participating.

Now, the new rules are, you can't "cherry pick", you can't red-line, you can't do the kinds of things you did in the past. You have to offer a good program at a reasonable price. And there will be



some churning out there. There's no doubt about it, under the new rules. But I want that churning to occur above the table, in the competitive marketplace.

That's why we have multiple purchasing cooperatives, and we allow agents to mix and match under the new rules, to be clear, competitive models to those purchasing cooperatives, without any exclusivity.

Where's it going to lead? I don't know. But I do believe, given the rules changes, and if they are not adequate, and the insurance agents are more creative than we think they are, you can always make sure that the restrictions and requirements on the sale of insurance are continually modified.

But the California experience with the voluntary purchasing cooperatives has reinforced my belief that all of the hypothetical downsides of this model, in fact, at least so far, don't exist.

Mr. GREENWOOD. Thank you. I have one other brief line of questioning.

Philosophically, I am drawn to the notion of the individual mandate. The most common criticism seems to be a question of enforceability. We've had the experiences of the automobile, and at least with the automobile, you can take the tags off, or confiscate the vehicle.

What are the enforcement mechanisms in your proposal?

Mr. THOMAS. We say that the universal mandate will go into effect in the year 2005. That gives us a 10 year wrap-up to the vouchering, to the reductions in the Medicare program, to provide up to, if in fact the reductions timetable is met, a buy-down up to 240 percent of the poverty level.

Following that, if in fact that's been done, or for any area that would otherwise receive a voucher, if we do not have enough money to cover that, the mandate does not apply.

But the mandate trigger in 2005 will be that anyone who does not then divide insurance, who is outside any of the voucherable support structure, does not have to live up to the mandate. But if they are within the vouchering structure, they will, upon the purchase of health care, have to pay 120 percent of the actual cost.

It seems to me, at some point, that society gets to say, "You want to go naked, fine. But you are going to have to make sure that society doesn't carry the cost." And if you otherwise would have been eligible under a structure which provides you with support and is otherwise available to you, and you choose not to do it, then the cost is 120 percent of the actual delivery cost.

Mr. GREENWOOD. That's the fee for the services, isn't that correct?

Mr. THOMAS. Yes. If you pay that two or three times, it's pretty dumb of you, because you'll sit down and pencil it out, given the broad insurance market, the creativity available in terms of a catastrophic plan or one that meets your particular needs, it's far cheaper to simply pick up that cost through the insurance structure. So, frankly, it's a carrot. It's an incentive.

But for people who are out there looking for the last potential person so that you can declare universal coverage, you've missed the point. Because when you examine the President's plan, you'll

find out that he is now going to start talking about the slippage, at which time you are going to reach universal coverage as well.

Frankly, I don't oppose the philosophical goal of the President in universal coverage. I just objected to the mechanism, which was to give it to everybody as the mother of all entitlements, and then not cover it.

And my question to the First Lady, the very first day of the Health Subcommittee hearings was, "You want to give the benefits to everybody, yes. Would you join me in saying that we won't extend the benefits until we've figured out a way to pay for them?" The answer was, "No."

That, I think, is not universal coverage, either, if you want to be honest and look at the behavior of this institution in the past on how we've "ponied-up" for benefits delivered. We provide it, but we say, Office of Management and Budget has to certify the savings have been made in the Medicare area before you apply the money to the vouchers.

Now, I think that's a positive incentive on us to make the reasonable reductions in those programs, and which the President and the First Lady have rightly said, plenty of room for adjustment. We just think not so much and not so fast, as they've advocated. Clearly, over a 10 year period, you're going to produce enough revenue to pay for those vouchers.

Now, if you don't pay for those vouchers, then, frankly, you haven't done your job. In terms of what the President says, and what the Democrats apparently say, isn't an achievable job—\$124 billion in 5 years, no. From 12 percent down to 7 percent continued increase in a 10 year period, that's pretty reasonable; and if we do that, universal coverage up to 240 percent of the poverty level through a voucher on the tax code, without a whole new bureaucracy in which to deliver the universal coverage mandate.

Mr. GREENWOOD. Thank you.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Greenwood.

Mr. McMillan?

Mr. McMILLAN. I apologize for being late.

Mr. THOMAS. Well, you missed some really good stuff.

Mr. McMILLAN. Well, I've read your bill, and I'm very tempted to sign onto it, and there's no particular reason why I haven't.

I just got appointed to the Entitlement Review Commission, which is going to have to go back and look at all this stuff, and come up with a recommendation by December 1st to affect next year's budget. So that's where I've been and why I'm late.

You and I have talked about this a lot. And I think the voucher concept is a very powerful one, that solves a lot of problems.

You could take the voucher approach, coupled with an individual mandate, means test it, and we've found ways to do that in a very affordable fashion, that probably expands the level of subsidiary, if you include everybody, even over what the President is doing, and can do it in a revenue-neutral manner. And I think there are a lot of elements of that in your approach.

But I've had questions raised, and I'm sure you've had, as to whether, in fact, the voluntary approach will deliver what I think probably all of the plans seek to achieve; and that is, to solve the

access problem, and to do so in a way that combines the weak in a way that they can get access in a competitive fashion to strong plans.

I happen to believe that with vouchers, which empower individuals, that the private market response will really be tremendous. Don't you share that view?

Mr. THOMAS. I do. And I think that with the changes of the rules, that as I say, a number of bills have—and frankly, we adopted a lot of your malpractice legislation. We pilfer from anybody who has good ideas.

In the areas in which the marketplace can work, I think will produce significant savings. And I think it's evident now as you involve individuals in these decisions, as is occurring now in the private sector, that there are savings that will be achieved.

But also, I have to tell you that I don't believe the competitive model will work in a "one size fits all" situation. I'm from California, and we've got the biggest State in the Union. There are 31 million people. But I represent an area within those 31 million people where there are a lot of miles between people.

And, frankly, a competitive model, just because you give someone a plastic card that says you've got coverage or a voucher that says you can get it, probably is not going to be able to get it in some of my areas. Frankly, mandatory health clinics and other government programs have brought health care to areas that we haven't had before.

We have a provision in our bill which will enhance those. We obviously assist in trying to get primary providers. We change the incentives away from the specialists. We have a tax credit for providers at \$1,000 a month, if they'll move out into more rural areas. So it's a combination of factors that will bring true universal coverage and true access to all Americans.

But you are absolutely right. For the vast majority and the bulk of people in the center, if we changed the rules and allow for a fair, competitive structure, with an ability to buy-down the costs for people to participate in that marketplace when they do not hold all of the cards otherwise, will, I think, not only produce real savings, but will continue those innovations in the private sector, leading to movement in the public sector.

And I believe the private sector drives the public sector in a lot of the health technology. I see that in other countries. And many of the other plans don't have—they don't have that private sector initiative-driving mechanism that I'm fearful of. If you have a single payor, where's the criticism; where's the structure?

So the private competitive model, nurtured and modified, is the one, I think, that does hold out a lot of promise, if you are honest about the real role of government, and how the two can complement each other, and not that one has to be the only model for the other. That isn't the way we do it now, and it's not going to be the way we do it tomorrow. But we ought to do both, smarter than we do today.

Mr. McMILLAN. Well, I think the voucher, coupled with the individual mandate, really gives that room to grow in.

What you end up with, under an approach more towards your side of the spectrum, is more competitive health care purchasing



groups out there, whether they be insurance companies or newly organized ones. And the challenge we've got is to generate competitive pressure on a limited number of providers.

You know, my community has got two major hospitals. That's a metropolitan area of about a million and a quarter people. There's some smaller hospitals, but the competitive pressure on them shouldn't come from a single State-managed health care alliance. It isn't going to generate that pressure.

Mr. THOMAS. No.

Mr. McMILLAN. It might fix prices and generate pressure, but it isn't going to generate a competitive pressure that multiple purchasing groups, all of whom have to adhere, at least, to certain standards that we could, and you would, prescribe in your bill, backed up by a voucher in terms of government funding—

Mr. THOMAS. So they can compete, who otherwise couldn't compete.

Mr. McMILLAN. Absolutely.

Mr. THOMAS. And then some anti-trust changes, so that health care professionals can make responsible choices in allocating health care dollars that they can't now. And the President has done some of this administratively. But, frankly, we can do a lot more statutorily.

And some of those doctors then can get involved in the administrative delivery structure. Because, frankly, if you have doctors being told what to do in terms of practice choices by MBA's, they are not going to do it. And we need a very active restructuring in which people have the right to fail, and those who come up with a new idea have a right to be rewarded over the next decade, so that we can continue to move forward with these changes.

To lock in something by government edict now, because some academician somewhere said they think it's a good idea, is absolutely crazy, speaking as an academician on leave.

Mr. McMILLAN. All right. One of the criticisms of your, or I'll say our, approach is that if you have an individual mandate, or if you have an individual voucher, and you don't keep the pressure on companies to provide insurance, that this somehow or another will undermine that.

Therefore co-pay comes and limits the size to 100 or less. I support co-pay, by the way, although I think it's got some flaws in it. But how do you respond to that criticism?

Mr. THOMAS. We spoke briefly to this before you came in. And, frankly, I'm concerned about that.

But I'm also concerned about the fact that the rules have been skewed in favor of increasing fringe benefits over reasonable wages by virtue of allowing folks to write that off. And some folks forget the very inequitable situation of writing off.

The Ways and Means Committee has been on again/off again about the self-employed. Currently, it's a bizarre 25 percent for self-employed. I don't know why somebody working for somebody gets 100 percent, and somebody who is self-employed gets only 25 percent.

What we do is take that tax cap, provide 100 percent for the self-employed, provide 100 percent for those who are paying for their own insurance who work for employers who do not provide it.



But we utilize—and the chairman has criticized, and I think, in part, rightly so—that the yardstick that we provide the health care is not as specific as you would like. I think there are downsides on that. We have a general structure that a board recommends changing on.

But now you have a uniform measuring stick out there. The collective bargaining process will make adjustments in those fringe benefits. I do not believe that the workers of America will lose benefits without having a significant portion of them replaced with wages. Right now, they have lost wages, because they have opted for the fringe benefits, sometimes, in not the best real world, free economic choice, but because the rules of the game slanted it in that direction.

I am open to any model which will show me that we can create a positive, supportive environment, to make sure the total compensation is not lost by employees through unscrupulous employers, as long as it isn't a device to hang onto a structure which guarantees that you don't get the cost improvements from people actually making choices in a real world situation; and that if they want this additional item, it's above the line, and you pay taxes on it.

Let me tell you, you take 40 percent of most of these broad cafeteria plans, take out the basic medical, and say, "Now, do you want this other stuff, if you're going to pay taxes on them?" And they'll say, "Heck, no, I don't want them. We threw it in because that was the game."

That's the kind of adjustment that needs to take place over the next 5 to 7 years, so that what we have under a tax cap is a reasonable program, but that we don't fund, through the taxpayers holding the bag, a lot of these various options that have driven the third party payor structure, and increased the costs unnecessarily in the structure.

So someone has got to convince me that the individual mandate is not the best way to go over an employer mandate, which perpetuates a lot of problems; and why, regardless of what we do, we don't put a reasonable tax cap in there, with whatever safeguards are necessary, to get people to begin looking at the decisions that they make.

Mr. MCMILLAN. The individual mandate, a mandate and voucher, which I then can use as an employee if I qualify, is an offset to putting the tax cap on a corporation in terms of deductibility. And that needs to really be developed in arguments for that approach, and I think it's an important one.

I don't think companies have health insurance plans because of tax deductibility. They've got a whole array of potential costs in running a business that are tax deductible, if they are looking for tax deductibility.

You know, it's easier to do something else than set up a health care plan, for goodness sakes. They do it because it's good employee relations, and I think that will continue.

Mr. THOMAS. I agree with you, up to a point. I believe you have to be competitive with a basic package nowadays, even more so today than yesterday, because employees are becoming more and more informed about it.

Mr. McMILLAN. But under an individual voucher plan, we're going to say, this voucher is only usable for an acceptable standard, basic package. So the company either has that, or the individual under that plan has the option to go out into the marketplace and find another plan.

Mr. THOMAS. Well, the producer has more responsible basic plans.

Mr. McMILLAN. Yes.

Mr. THOMAS. But then it requires you to look at that marginal addition, which used to not get much focus because, heck, throw it in. You know, we don't have to worry about it.

Mr. McMILLAN. Yes.

Mr. THOMAS. I agree with you, the basic plan is not necessarily driven by the tax codes.

But I've got to tell you that a lot of these areas on the third player—you know, the vision, the paid prescription, the double dental—those are driven, in part, by the tax code. Those are the things that people don't make decisions about. And if they had to pay a decent co-pay, or they had to pay a rider out of their own pocket for it, they would say it's not worth it.

Mr. McMILLAN. I think you're arguing for nondeductibility of that type of coverage, right?

Mr. THOMAS. I'm willing to let them have it, but just require them to pay taxes on it. That will sober the whole process up.

Mr. McMILLAN. It raises revenue and reduces benefits.

Mr. THOMAS. Yes. Well, it's a nice cost check on benefits, and it provides enough money to cover 100 percent self-employed and 100 percent people who pay their own insurance who work for corporations, and \$7.7 billion left over, to begin to buy down those vouchers that we are going to use to the tax code to allow people to have health care who now can't afford it.

Mr. McMILLAN. Thank you very much.

Mr. WAXMAN. Mr. Thomas, I want to commend you on your efforts and your presentation. We certainly look forward to working with you.

Mr. THOMAS. I look forward to working with somebody.

Mr. WAXMAN. Well, if you can't find anybody else, you can work with me.

Mr. THOMAS. Thank you very much, Mr. Chairman.

Mr. WAXMAN. That concludes our hearing for today. We stand adjourned.

[Whereupon, at 4:15 p.m., the hearing was adjourned.]



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